日本臨床検査標準協議会会誌　18(1):3-41　2003

Ⅰ．臨床検査関係 ISO 国際規格の用語とその邦訳語

Ver.1.1　2003-02-14

Terminology of the ISO International Standard on the Clinical Laboratory and the Japanese Translation Word

日本臨床検査標準協議会 (JCCLS) 用語委員会
Committee on Terminology of JCCLS

日本臨床検査標準協議会（JCCLS）用語委員会では、ISO 国際規格のうち、臨床検査に関わる国際規格（212 専門委員会担当分）の翻訳に使用される訳語を統一する目的で、本用語とその邦訳語集を作成した。

該当国際規格を翻訳する場合、Term 列に示された用語について、定義 / 用例列に示された意味で使用されている場合は本邦訳語を適用する。

本表の作成には次の資料を使用した。

1. DIS 15189 Medical laboratories-Particular requirements for quality and competence
2. DIS 15190 Clinical Laboratory medicine-Safety management for medical laboratories
3. DIS 15193 In vitro diagnostic systems-Measurement of quantities in samples of biological origin-Requirements and layout of reference measurement procedures
4. DIS 15194 In vitro diagnostic systems-Measurement of quantities in samples of biological origin-Description of reference materials
5. DIS 15195 Requirements for reference measurement laboratories in laboratory medicine.
6. DIS 15196 Determination of analytical performance goals for laboratory procedures based on medical requirements
7. DIS 15197 Requirements for in vitro blood glucose monitoring systems for self-testing in managing diabetes mellitus
8. DIS 15198 Clinical laboratory medicine-In vitro diagnostic medical devices-Validation of manufacturer' s recommendations for user quality control
9. DIS 17511 In vitro diagnostic medical devices-Measurement of quantities in samples of biological origin-Metrological traceability of values assigned to calibrators and control materials
10. DIS 18153 In vitro diagnostic medical devices-Measurement of quantities in samples of biological origin-Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials
11. DIS 19001 In vitro diagnostic medical devices-Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology
12. ISO/TC212 N124 Glossary

臨床検査関係 ISO 国際規格の用語とその邦訳語

	語　彙	邦訳語	摘　要	定　義・用　例
1	accelerated stability study	加速安定性試験	accelerated test で加速試験 (JIS Z 8115)	(定義) stability study designed to increase the rate of chemical or physical degradation of an in vitro diagnostic reagent by using exaggerated conditions with the purpose of predicting the shelf-life
2	acceptable quality level	許容品質水準		(定義) when a continuous series of batches is considered, the quality level which for the purposes of sampling inspection is the limit of a satisfactory process average
3	acceptance testing	抜き取り検査		(定義) process of inspecting a portion of the units of product that make up a batch (i.e. the sample) for the purpose of accepting or rejecting the entire batch, as prescribed in the associated (pre-established) sampling plan
4	accepted reference value	許容基準値		(用例) ISO 3534-1, instead of "a true value" in the definition above, uses the concept "the accepted reference value", which can be a theoretical (true), assigned, consensus, or procedure-defined value.
5	accuracy	精確さ	JIS Z 8402	(定義) the extent to which the mean of repeated measurements, conducted on a given sample, approaches the blood glucose concentration in the sample as measured by the comparative method designated by the manufacturer (用例) The term accuracy, when applied to a set of test results, involves a combination of random components and a common systematic error or bias component.
6	active ingredient	反応成分		(定義) a constituent that participates in the reaction used to measure or detect the analyte
7	additive	添加剤		(定義) any substance, other than surface treatment designed to be irremovable, that is placed inside the receptacle to facilitate the preservation of the specimen, or is placed in, or on, any receptacle accessory in order to allow the intended in vitro diagnostic examination to be performed (用例) The primary sample collection manual shall include procedures for primary sample collection (e.g., phlebotomy, skin puncture, blood, urine and other body fluids.) with descriptions of the primary sample containers and any necessary additives.
8	analyte	分析成分		(定義) component indicated in the name of a measurable quantity (用例) Traceability of calibration requires that the reference and routine measurement procedures measure the same measurable quantity with an analyte of the same pertinent characteristics.

9	analytical error	分析誤差		(定義) the upper limit of analytical error (i.e., bias, imprecision, nonspecificity) that can be tolerated without affecting the clinical use of an assay (用例) In relation to the evaluations, the analytical performance should be characterized in terms of total analytical error.
10	analytical portion	分析部分		(定義) Portion of material taken from the analytical sample and on which the measurement or observation is actually carried out (用例) The estimated within- and between-sample homogeneity, with regard to the minimum analytical portion, shall be stated.
11	analytical sample	分析試料		(定義) sample prepared from the laboratory sample and from which analytical portions may be taken (用例) The steps in the preparation of the analytical sample shall be described, e.g. separation, grinding, mixing, freeze drying, storage, and reconstitution.
12	analytical sensitivity	分析感度		(用例) performance specifications (e.g., linearity, precision, accuracy as expressed as standard uncertainty of measurement, detection limits, measuring interval, systematic error, analytical sensitivity, and analytical specificity);
13	analytical solution	分析溶液	analytical は分析に統一	(定義) Solution prepared by dissolving, with or without reaction, an analytical portion in a gas, liquid, or solid (用例) The preparation of any analytical solution shall be described.
14	analytical specificity	分析特異性		(定義) Ability of a measurement procedure to determine solely the measurable quantity it purports to measure (用例) Manufacturer's standing measurement procedure shall define a measuring system which is calibrated by one or more of the manufacturer's working calibrators or higher types of calibrator and is validated for analytical specificity.
15	annex	附属書	日本規格協会訳語	(用例) 一般的な表題
16	antibody	抗体		(定義) Specific immunoglobulin formed by B-lymphocytes in response to exposure to an immunogenic substance and able to bind to this (用例) This problem is typically met in immunoprocedures, where antibodies used In different procedures can have different reactivity towards the epitope(s) of the analyte antigen or the antigens used as reagents can have different reactivity towards the analyte antibody.

	語　彙	邦訳語	摘　要	定　義・用　例
17	antiseptic	消毒薬		(定義) compound or application of compound to skin or mucous membranes to substantially reduce microorganism content (用例) Laboratories should provide alternate materials for hand washing for workers who suffer from allergies or other reactions to specific compounds contained in certain antiseptic agents.
18	arbitrary unit	任意単位		(用例) Where an arbitrary unit is used it shall have an internationally agreed definition or a definition described by a given measurement procedure.
19	assigned value	表示値		(定義) value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose (用例) Laboratory medicine routinely provides results for 400 to 600 types of quantity. For most of these, the traceability of the assigned value for a product calibrator stops after only one metrologically higher step consisting of a (reference) measurement procedure, or after two steps consisting of a measurement procedure and a (reference) calibrator.
20	batch	バッチ		(定義) defined amount of material, either starting material, intermediate or finished product, which is uniform in its properties and has been produced in one process or series of processes [EN 375 : 2000] (用例) For the first batch of such a material, an "international unit" is defined as an arbitrarily specified amount of the material and characterized by its specified biological activity.
21	batch acceptance	バッチ確認手順		(定義) procedure of establishing conformity of a batch with the device specifications
22	batch code	バッチ番号		(定義) a code that is a distinctive combination of numbers and/or letters which specifically identifies a batch and permits its manufacturing history to be traced
23	bias	かたより	JIS Z 8402	(定義) difference between the expectation of the results of measurement and a true value of the measurand (用例) Data from EQAS/PT programs provide an estimate of the total error that is available with current technology, because the analytical errors derived from EQAS/PT include both between- and within-laboratory error, the precision and bias estimates are the maximum total error for a specific measurement.

24	biological reference interval	生物学的基準範囲		(定義) reference interval. central 95-percent interval of the distribution of reference values (用例) Biological reference intervals shall be periodically reviewed. If the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population, then an investigation shall be undertaken, followed, if necessary, by corrective action.
25	biological safety cabinet	感染防御キャビネット		(定義) primary containment device for working with infectious agents (用例) When risk of infection associated with aerosols is possible, samples shall be opened and worked on only in a biological safety cabinet.
26	blood glucose monitor	血糖モニター		(定義) the instrument component of a blood glucose monitoring system, commonly referred to as a "meter." (用例) If eight or fewer replicate results fall within the specified quality control range, the blood glucose monitor has failed the high temperature test.
27	blood glucose monitoring system	血糖モニターシステム	ISO/TC 212 国内検討委員会 03/02/10	(定義) a measuring system which is intended by the manufacturer to be used in vitro on blood samples derived from the human body for the purpose of monitoring blood glucose concentrations (用例) The following protocol shall be used to evaluate the repeatability of the blood glucose monitoring system.
28	calibration	校正	JIS Z 8103	(定義) set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards (用例) Manufacturer's product calibrator shall have its value assigned according to the manufacturer's standing measurement procedure and is intended for calibration of the end-user's routine measurement procedure.
29	calibration function	校正関数		(用例) These records may include – – – g) calibration functions and conversion factors;
30	calibration hierarchy	校正の階層段階		(用例) In such cases, trueness is referred to that level of the calibration hierarchy until an internationally agreed reference measurement procedure and/or calibrator becomes available.
31	calibration material	校正物質		(定義) reference material whose value is used for the independent variable in a calibration function (用例) The calibration material shall have demonstrated commutability as regards the manufacturers selected measurement procedure and the procedure to be calibrated.

	語　彙	邦訳語	摘　要	定　義・用　例
32	calibrator	検量物質		(定義) substance, material or article intended by its manufacturer to be used to establish the measurement relationships of an in vitro diagnostic medical device (用例) Manufacturer's standing measurement procedure shall define a measuring system which is calibrated by one or more of the manufacturer's working calibrators or higher types of calibrator and is validated for analytical specificity.
33	capability	能力		(用例) The review of capability may include results of earlier participation in interlaboratory comparisons or external quality assessment schemes and/or the running of trial examination programmes in order to demonstrate uncertainties of measurement, limits of detection, etc.
34	case-finding	症例検討		(定義) investigations to discover possible causes of symptoms of a patient (用例) For the purpose of this document, case finding is defined as the performance of tests on an opportunistic basis when an individual presents to the health care system with a complaint unrelated to the tests performed. Examples include testing conducted when individuals visit hospitals for one problem and arbittery of investigations is performed or when they visit general practitioners with a medical complaint or for routine "healthy check-up".
35	catalytic activity	触媒活性		(定義) property of a component corresponding to the catalysed substance rate of conversion of a specified chemical reaction, in a specified measurement system. (用例) For the measurement of the catalytic activity concentration of enzymes (hereafter called 'catalytic concentration'), a hierarchy of calibrators and measurement procedures is described in the present standard.
36	catalytic concentration	触媒濃度		(定義) catalytic activity of a component divided by volume of the original system (用例) Enzymes in blood or other biological fluids can be measured for diagnostic purposes in terms of their catalytic concentrations.
37	catalytic-activity concentration	触媒活性		(定義) catalytic activity of a component divided by volume of the original system (用例) Results of catalytic-activity concentration measurements are only comparable if the enzyme activities are measured under the same conditions.

38	certified reference material	認証標準物質		(定義) reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence (用例) The material usually is highly purified containing a physicochemically well-defined analyte, examined for stability, compositional integrity, and accompanied by a certificate (certified reference material, CRM).
39	chromogenic reagent	発色試薬		(定義) Reagent that reacts with certain chemical groups present or induced in cells and tissues with the formation of a coloured compound in situ.
40	cleaning	洗浄		(定義) process to remove all visible debris (用例) Specific protocols shall be established for the decontamination, cleaning, and disinfections of each piece of equipment in case of accidents or spills that result in biological, chemical, or radioactive contamination, and also prior to equipment being serviced or repaired.
41	clinical laboratory	臨床検査室		(定義) a facility for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing examination are not considered laboratories. A laboratory may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation. (用例) Additives for reference materials used in the clinical laboratory include anticoagulants, antioxidants, antimicrobial agents, stabilisers, wetting agents, and coating of pellets.
42	clinical laboratory sciences	臨床検査科学		(用例) International Union of Pure and Applied Chemistry, International Federation of Clinical Chemistry. Compendium of terminology and nomenclature of properties in clinical laboratory sciences.

	語彙	邦訳語	摘要	定義・用例
43	closing torque	締付けトルク		(定義) twisting force, specified by the manufacturer, that is required to tighten a screw threaded closure sufficiently, by means of a torque wrench, to effect the sealing of a receptacle
44	closure	ふた		(定義) component by which the container is closed (用例) The container and/or packaging shall be specified as to type, material, closure, and atmosphere.
45	combined uncertainty	合成不確かさ		(用例) a combined uncertainty Uc obtained as the outcome of an uncertainty budget
46	commutability	互換性		(用例) The analytical specificities of the described routine procedure and metrologically higher reference measurement procedures as well as the stability and commutability of the calibrators shall be known or investigated.
47	comparability	整合性		(定義) Comparison with results obtained by other procedures If relevant for comparability, comparative data shall be given on results of measurements on various types of sample to which the reference measurement procedure is claimed to apply with the procedure presented and with alternative measurement procedures differing in principle of measurement, method of measurement, or details of measurement procedure. (用例) International agreement on such reference measurement systems without traceability to SI i s necessary to avoid nal or regional reference measurement systems provide different traceability chains giving different results.
48	comparative method	比較対照法		(定義) a method designated by the manufacturer as the appropriate analytical system for establishing specimen glucose target values for accuracy determinations (用例) The U.S. Food and Drug Administration issued a draft guidance document in 1998 (Reference 17) for blood glucose monitoring devices that employ enzymatic reagent systems. The document indicates that generally accepted performance criteria are as follows: at glucose concentrations >= 5,5 mmol/L (100 mg/dL), 95% of the glucose results shall fall within +/− 20 % of a well-characterised comparative laboratory method or other legally marketed glucose method, and at glucose concentrations < 5,5 mmol/L (100 mg/dL), 95% of the results shall fall within +/−1,11 mmol/L (20 mg/dL) of the comparative method.

49	competence	適合能力		(用例) This International Standard specifies particular requirements for the quality and competence of medical laboratories. It covers all examinations and provides guidance for laboratory procedures to ensure quality and competence in medical laboratory examinations.
50	component	構成要素		(用例) Computer components and storage areas should be readily accessible to appropriate fire-fighting equipment.
51	conformity	適合性		(用例) The laboratory management shall have a policy and procedure to be implemented when it detects that any aspect of its examinations does not conform with its own procedures or the agreed upon requirements of its quality management system or the requesting clinician. These shall ensure that: —— h) each episode of nonconformity is documented and recorded. These records shall be reviewed at regular specified intervals by laboratory management to detect trends and initiate preventive action.
52	container	容器		(定義) part of the receptacle without the closure, and without any accessory, that contains the specimen (用例) Storage conditions for the unopened container shall be given, e.g. temperature, humidity, and iight.
53	control material	管理物質		(定義) substance, material or article intended by its manufacturer to be used to verify the performance characteristics of an in vitro diagnostic medical device (用例) The trueness of measurement of a value assigned to a defined quantity of a calibrator or trueness control material, depends on the metrological traceability of the value through an unbroken chain of alternating measurement procedures and measurement standards (calibrators), usually having successively decreasing un-certainties of measurement
54	control procedure	管理手順		(定義) activities routinely performed in order to monitor the adequacy of the method and test system, and to indirectly assess the accuracy and precision of results (用例) These quality control procedures are intended to provide users with assurance that the device is performing within specifications, and therefore the results are suitable for its diagnostic use.
55	control strain	標準株		(定義) Microorganism used for microbial performance evaluation of culture media.
56	conversion factor			(用例) These records may include - - - g) calibration functions and conversion factors;

	語　彙	邦訳語	摘　要	定　義・用　例
57	co-ordinator of a performance evaluation study	性能評価責任者		(定義) person empowered by the manufacturer with responsibility for the entire performance evaluation study of an in vitro diagnostic medical device
58	corrective action	是正処置		(用例) Procedures for corrective action shall include an investigation process to determine the underlying cause(s) of the problem. These shall, where appropriate, lead to preventive actions.
59	coverage factor	包含係数		(用例) Accuracy of measurement – – – b) an expanded uncertainty U with the coverage factor k specified (U = k – u,).
60	critical value	緊急異常値		(用例) In addition to document control identifiers, documentation should include—— m) alert/critical values, where appropriate
61	cross reaction	交差反応		(用例) In addition to document control identifiers, documentation should include—— i) interferences (e.g. lipemia, hemolysis, icterus) and cross reactions
62	decontamination	汚染除去		(定義) destruction or removal of microorganisms to some lower level, but not necessarily to destruction, to render materials safe for further handling (用例) Rubbish and laboratory waste shall not be allowed to accumulate. Filled containers shall be removed from work areas on a regular basis. They shall be held in a designated secure place, normally within the laboratory area, prior to decontamination or final disposal.
63	detection limit	検出限界		(用例) performance specifications (e.g. linearity, precision, accuracy as expressed as standard uncertainty of measurement, detection limits, measuring interval, systematic error, analytical sensitivity, and analytical specificity);
64	deterioration	劣化		(用例) For reference materials of higher order, a stability allowing storage life from 8 to 10 years of use is a relevant aim. It is often possible to estimate how the decomposition will take place with time by exposing samples for relatively short periods (e.g. several weeks) to a range of temperatures, including some at which deterioration will occur more rapidly than at the proposed storage temperature.
65	determination	測定		(用例) Alternatively, the blood glucose monitoring system shall be rendered nonfunctional and shall not display a numerical glucose determination.

66	diagnostic test	診断用検査		(定義) a measurement or examination of a diagnostic specimen for the purpose of diagnosis, prevention, or treatment of any disease or the assessment of health or impairment of health of an individual patient (用例) Technical Committee ISO/TC 212: Clinical laboratory testing and in vitro diagnostic test systems
67	difference scale	差分尺度		(用例) Each value of a quantity assigned to such a material, intended for use with measurement procedures, is found on a difference scale or a ratio scale, is expressed as a numerical value multiplied by a unit of measurement (see 4.1), and is accompanied by an uncertainty of measurement.
68	disinfection	消毒		(定義) elimination of all vegetative pathogenic bacteria, including M. tuberculosis, but not necessarily viruses or spores (用例) Specific protocols shall be established for the decontamination, cleaning, and disinfection of each piece of equipment in case of accidents or spills that result in biological, chemical, or radioactive contamination, and also prior to equipment being serviced or repaired.
69	draw volume	採取量		(定義) amount quantity of liquid specimen drawn into an evacuated receptacle
70	EQAS	外部品質評価スキーム、外部精度評価スキーム		
71	EQAS organization	ＥＱＡＳ団体		(定義) organization that designs and organizes an external quality assessment scheme (用例) The systems for the surveillance of medical laboratory performance from an external source are known as external quality assessment schemes (EQAS) in Europe and proficiency testing (PT) in the USA (26).
72	evacuated receptacle	真空試料採取容器		(定義) receptacle intended for specimen collection by means of evacuation, either already induced by the manufacturer (i. e. pre-evacuated receptacle), or induced by the user immediately before a liquid specimen is taken
73	examination	検査		(定義) set of operations having the object of determining the value of a property (用例) For those examinations which are performed using different procedures or equipment and/or at different sites, there shall be a defined mechanism to verify the comparability of results throughout the clinically appropriate intervals.

	語　彙	邦訳語	摘　要	定　義・用　例
74	examination procedure	検査手順		(定義) set of operations, described specifically, used in the performance of examinations according to a given method (用例) The laboratory shall make its list of current examination procedures, including primary sample requirements and relevant performance specifications and requirements available to users of laboratory services upon request.
75	expanded uncertainty	拡張不確かさ		(用例) 4.14.11 Accuracy of measurement − − − b) an expanded uncertainty U with the coverage factor k specified (U = k − u,).
76	expected variability	期待変動		(用例) 7.7 The expected variability of comparison around the regression line (prediction limits) may be estimated at a given probability on the basis of the number of samples and the respective uncertainties of the two measurement procedures.
77	expiry date	有効期限		(定義) the date up to which product performance is assured by the manufacturer based on the stability of the IVD reagent [EN 375 : 2000]
78	external quality assessment	外部品質評価、外部精度評価		(用例) The quality management system shall include, but not be limited to, internal quality control and participation in organized interlaboratory comparisons such as external quality assessment schemes.
79	extraction hood	排気フード		(定義) cover above laboratory device for the extraction of air or fumes which prevents their general circulation (用例) Equipment generating excessive steam or odour shall be isolated from the general workspace, under a suitable extraction hood.
80	failure mode, effect and criticality analysis (FMECA)	故障モード、影響、および致命度解析(FMECA)		(定義) systematic review of a system or product involving three phases: identification of potential failures, assessing the impact on total system/product performance of that failure, and the criticality of that failure (用例) The manufacturer shall conduct an appropriate risk analysis, such as failure mode, effect and criticality analysis (FMECA) or fault tree analysis (FTA), during the design and development of the device.
81	fault tree analysis (FTA)	故障の木解析		(定義) systematic review of a system or product to identify sources of potential failure; particularly useful in safety and reliability analyses (用例) The manufacturer shall conduct an appropriate risk analysis, such as failure mode, effect and criticality analysis (FMECA) or fault tree analysis (FTA), during the design and development of the device.
82	fill line	充填標線		(定義) mark on a container, or its label, to indicate the nominal liquid capacity of a container, or filling capacity of a receptacle

83	filling capacity	採取容量		(定義) volume of specimen needed to achieve the required additive to blood ratio
84	fluorochrome	蛍光色素		(定義) Reagent which emits visible light when irradiated with excitation light of a shorter wavelength. (用例) A description shall be provided giving guidelines for staining in biology and for qualitative and quantitative procedures (if applicable). This shall include information on:—— b) details of a suitable reaction procedure used by the manufacturer for testing the reactivity of the dye, stain, chromogenic reagent, fluorochrome, antibody, nucleic acid probe, or lectin used for staining in biology;——
85	free space	遊び空間		(定義) extra capacity, or headspace, which is provided to allow adequate mixing of the contents of a receptacle
86	graduation mark	標線		(定義) mark on a container, or its label, to enable an estimation to be made of the volume of the specimen
87	gravimetric analysis	重量分析	JIS K 0211	(定義) method of determining the volume of a liquid by weighing and correcting for the mass density of the liquid
88	hierarchy	階層段階		(用例) d) place in a hierarchy of measurement procedures and traceability.
89	histopathology	組織病理学		(用例) The laboratory shall have an effective, documented procedure for evaluating and selecting referral laboratories as well as consultants who are to provide second opinions for histopathology, cytology, and related disciplines.
90	holder and suction tip assembly	液状試料採取用具		(定義) device that is intended to be attached to an evacuated receptacle to enable liquid sample collection to be performed
91	housekeeping	日常業務		(用例) Measures shall be taken to ensure good housekeeping in the laboratory.
92	immediate container	直接容器		(定義) packaging which protects the contents from contamination and/or other effects of the external environment (用例) Detailed instructions for use shall be provided, including at least the following information as appropriate: —— b) opening of the immediate container: —
93	imprecision	不精密さ		(定義) dispersion of independent results of measurements obtained under specified conditions (用例) When one's own internal QC data is used to establish quality specifications for imprecision, an average of the error over an extended time period, e.g., six months, can be used to average out errors from multiple lots of reagent, different technologists, etc

	語　彙	邦訳語	摘　要	定　義・用　例
94	in vitro diagnostic instrument (IVD instrument)	体外診断用医用機器		(定義) Any instrument which, used alone or in combination with other in vitro diagnostic medical devices, is intended by the manufacturer wholly or mainly to be used in vitro for the examination of substances derived from the human body for the purpose of providing information relevant to the detection, diagnosis, monitoring or treatment of physiological states, states of health or disease, or congenital abnormality.
95	in vitro diagnostic medical device	体外診断用医薬品・医療機器	ISO/TC212 国内検討委員会 03/02/10	(定義) any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state, or concerning congenital abnormality, or to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures (用例) The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, in vitro diagnostic medical devices.
96	in vitro diagnostic reagent (IVD reagent)	体外診断用医薬品		(定義) Reagent that, used alone or in combination with other in vitro diagnostic medical devices, is intended by the manufacturer to be used in vitro for examination of substances derived from human, animal or plant sources, for providing information relevant to the detection, diagnosis, monitoring or treatment of physiological states, states of health or disease, or congenital abnormality. (用例) This International Standard relates to EN 375, In vitro diagnostic systems – Requirements for labelling of in vitro diagnostic reagents for professional use and EN 376, In vitro diagnostic systems – Requirements for labelling of in vitro diagnostic reagents for self testing and should be used in conjunction with these.
97	in vitro diagnostic systems (IVD systems)	体外診断検査システム (IVD システム)		(用例) 全体のテーマ名
98	infectious biological material	感染性生物試料		(定義) material which is known or highly likely to contain viable microorganisms or other transmissible agents (e. g. prions) which are known or suspected to cause disease in humans
99	influence quantity	影響量		(定義) Quantity that is not the measurand but that affects the result of the measurement (用例) A specified cause of a matrix effect is an influence quantity.

100	inspection by attributes	出荷検査		(定義) inspection method whereby either the unit of product is classified simply as conforming or nonconforming with respect to a given requirement or set of requirements
101	inspection by variables	抜取出荷試験		(定義) inspection method whereby a specified quantitative property is measured to establish statistically the acceptability of a batch from the result obtained from the units of product, either components or finished devices, in a sample
102	instructions for use	取扱説明		(定義) information supplied by the manufacturer with an IVD instrument concerning the proper use and the safe and correct operation, maintenance and basic trouble-shooting of the IVD instrument (用例) The responsibility of the manufacturer for metrological traceability shall begin at the assigned value for a product calibrator and end at the secondary calibrator or secondary reference measurement procedure as the case may be and if such exist. (The former segment is delimited by two horizontal broken lines). The manufacturer, however, shall also be responsible for the instructions for use.
103	interference	干渉		(定義) Systematic error of measurement caused by an influence quantity which does not by itself produce a signal in the measuring system, but which causes an enhancement or depression of the value indicated (用例) In addition to document control identifiers, documentation should include – – i) interferences (e.g., lipemia, hemolysis, icterus) and cross reactions; – – – .
104	interference	障害		(用例) Attention should be paid to biological sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate, to the technical activities concerned.
105	interlaboratory comparison	検査室間比較		(用例) The laboratory shall participate in organized interlaboratory comparisons, such as external quality assessment schemes, that encompass the extent and complexity of examination procedures used by the laboratory.
106	internal quality control	内部品質管理、内部精度管理		(定義) operational techniques and activities at the point of use that are used to fulfil requirements for quality of services (用例) The quality management system shall include, but not be limited to, internal quality control and participation in organized interlaboratory comparisons such as external quality assessment schemes.

	語　彙	邦訳語	摘　要	定　義・用　例
107	international conventional calibration material	国際常用校正物質		(定義) calibrator material whose value of a quantity is not traceable to the SI but is assigned by international agreement (用例) When appropriate the available highest level procedure or calibrator shall be an international conventional reference measurement procedure or an international conventional calibration material endorsed by an international metrological body or an international scientific organization.
108	international conventional reference measurement procedure	国際常用基準測定操作法		(定義) measurement procedure yielding values that are not traceable to the SI but which by international agreement are used as reference values for a defined quantity (用例) When appropriate the available highest level procedure or calibrator shall be an international conventional reference measurement procedure or an international conventional calibration material endorsed by an international metrological body or an international scientific organization.
109	international measurement standard	国際測定標準		(定義) standard recognized by an international agreement to serve internationally as the basis for assigning values to other standards of the quantity concerned
110	inventory control system	在庫管理システム		(用例) There shall be an inventory control system for supplies.
111	investigator	評価責任者		(定義) person responsible for the execution of (a part of) the performance evaluation at a certain location
112	kit	キット		(定義) set of components (reagents and/or other materials) packaged together (用例) Each new version of examination kits with major changes in reagents or procedure shall be checked for performance. Any procedural changes shall be dated and authorized as for other procedures.
113	kit component	キット構成品		(定義) in vitro diagnostic medical device intended to be part of a kit
114	label	ラベル		(定義) printed, written or graphic information placed on a container (用例) The labels of the immediate container and the outer container shall be in accordance with EN 375. The product name on the label shall be in accordance with clause 4.

115	labeling	添付情報		(定義) all printed, written, graphic, or other information affixed to, or accompanying an in vitro diagnostic medical device including labels on any of its packaging, users' manuals, and package inserts (用例) The laboratory shall, if relevant, have a documented procedure for the receipt, labelling, processing, and reporting of those primary samples received by the laboratory and specifically marked as urgent.
116	laboratory capability	検査室能力		(定義) necessary physical, environmental, and information resources, personnel, skills, and expertise necessary for the performance of the examinations in question (用例) The review of laboratory capability may include results of earlier participation in interlaboratory comparisons or external quality assessment schemes and/or the running of trial examination programmes in order to demonstrate uncertainties of measurement, limits of detection, etc.
117	laboratory director	検査部長		(定義) a person or persons who have the competence to assume the responsibility and authority for the laboratory (用例) The responsibilities of the laboratory director or designees shall include professional, scientific, consultative or advisory, organizational, administrative, and educational matters.
118	laboratory management	検査室管理チーム		(定義) those persons who manage the activities of the laboratory headed by the laboratory director (用例) The laboratory management shall authorize personnel to perform particular tasks such as sampling, examination, operation of particular types of equipment, including use of computers in the laboratory information system.
119	laboratory sample	検体		(定義) Primary sample or a subsample of it as prepared for sending to or as received by the laboratory and intended for measurement (用例) Storage of the primary sample and other laboratory samples shall be in accordance with approved policy.
120	laboratory services	検査サービス		(用例) Medical laboratory services are essential to patient care and therefore should be available to meet the needs of all patients and clinical personnel responsible for human health care.
121	lay person	非専門家		(定義) individual who does not have specific medical education (用例) The primary goal of the standard is to establish requirements that result in acceptable performance when used by lay persons and to specify procedures for user verification by which conformance to performance criteria can be demonstrated

	語　彙	邦訳語	摘　要	定　義・用　例
122	lay user	一般使用者		(定義) an individual intended user who is not a laboratory professional who uses an analytical system for the management of his/her clinical condition (e.g., diabetes mellitus) or the confirmation of the presence of an analyte (e.g., hCG in pregnancy) (用例) Blood samples are very complex and highly variable. Calibration by the lay user is not practical.
123	level of confidence	信頼限界		(用例) average and expanded uncertainty giving an interval estimated to have a level of confidence of 0,95.
124	lifetime	有効期間		(用例) Procedures for monitoring the stability of the reference material during its lifetime involve measurement of characteristic quantities at planned intervals during the time in which the reference material will be used; for i instance measurement of haemoglobin concentration in the plasma of a reference preparation of stabilized blood.
125	limit of detection	検出限界		(用例) The term "analytical sensitivity" is not a synonym for the concept "limit of detection" (see 4.14.14), although it is often so defined.
126	limiting quality	最低限度の品質		(定義) when a batch is considered in isolation, a quality level which, for the purposes of sampling inspection, is limited to a low probability of acceptance
127	linearity	直線性		(用例) performance specifications (e.g. linearity, precision, accuracy as expressed as standard uncertainty of measurement, detection limits, measuring interval, systematic error, analytical sensitivity, and analytical specificity);
128	logbook	業務日誌		(用例) 4.18 Quality assurance If a clause on quality assurance is included, it shall discuss as appropriate: a) internal quality control; b) logbook(s); c) external quality assessment.
129	lot	ロット		(定義) a defined amount of material, either starting material, intermediate or finished product, which is uniform in its properties and has been produced in one process or series of processes
130	lyophilized material	凍結乾燥物質		(用例) 5.4 Scope: – – – d) mentioning of major required pretreatment of the reference material which is not performed on the biological samples according to a specified measurement procedure (for example, reconstitution of lyophilized material).
131	maintenance	保守		(用例) The laboratory management shall have responsibility for the design, implementation, maintenance, and improvement of the quality management system.

132	management of patient	患者マネジメント		(用例) The services should also include active participation in prevention of disease together with diagnosis and management of patients.
133	management review	マネジメントレビュー		(用例) All of these quality records shall be available for laboratory management review.
134	manufacturer	製造業者		(定義) person or organization who designs, manufactures, fabricates, assembles, or processes a finished device (用例) When a manufacturer of an IVD medical device recommends a quality control procedure for the user to monitor device performance, the manufacturer shall describe in the instructions for use all requirements and all actions to be taken by the user (e.g., acceptable control materials, ---- and actions to be taken upon observing unacceptable quality control data).
135	manufacturer's standing measurement procedure	製造業者社内標準測定操作法		(定義) a measuring system which is calibrated by one or more primary or secondary calibrators (用例) For blood glucose meters, accuracy is measured by the extent to which measurements of blood samples from different patients agree with the blood glucose concentrations in the samples as measured by the manufacturer's standing measurement procedure.
136	manufacturer's selected measurement procedure	製造業者自社推奨測定操作法		(用例) In many cases, at present, there is no traceability above the manufacturer's selected measurement procedure or the manufacturer's working calibrator.
137	manufacturer's working calibrator	製造業者実用キャリブレーター		(用例) In many cases, at present, there is no traceability above the manufacturer's selected measurement procedure or the manufacturer's working calibrator.
138	material safety data sheets	製品安全データシート（ＭＳＤＳ）		(定義) technical bulletins provide detailed hazard and precautionary information (用例) The plan shall include - - - procedures for obtaining, maintaining, and distributing Material Safety Data Sheets (MSDS) for each laboratory chemical used (to ensure that employees have 24-hour access to this information).
139	matrix	マトリックス		(定義) all components of a material system, except the analyte (用例) One limitation is not using actual blood samples, since each system may be affected differently by an artificial matrix.
140	measurable quantity	可測量		(定義) attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively
141	measurand	測定対象物質		(定義) Particular quantity subject to measurement (用例) Precision of measurement cannot be given a numerical value in terms of the measurand, only descriptions such as 'sufficient' or 'insufficient' for a stated purpose.

	語　彙	邦訳語	摘　要	定　義・用　例
142	measurement	測定		(定義) set of operations having the object of determining a value of a quantity (用例) The environment in which the primary sample collection and/or examinations are undertaken shall not invalidate the results or adversely affect the required quality of any measurement.
143	measuring curve	測定曲線		(用例) 4.14.5 Linearity or other form of analytical measuring curve When appropriate, the linear portion of the measuring curve shall be stated as an interval of quantity values.
144	measuring function	測定関数		(用例) The analytical measuring function shall be used when converting a measured response into a measured value of a quantity.
145	measuring interval	測定範囲		(用例) performance specifications (e.g., linearity, precision, accuracy as expressed as standard uncertainty of measurement, detection limits, measuring interval, systematic error, analytical sensitivity, and analytical specificity
146	measuring system	測定システム		(用例) A programme for calibration of measuring systems and verification of trueness shall be designed and performed so as to ensure that measurements are traceable to the SI units or by reference to a natural constant.
147	medical laboratory	臨床検査室		(定義) laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haemotological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, treatment of disease in, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or microorganisms. Facilities which only collect or prepare specimens, or act as a mailing or distribution centre, are not considered to be laboratories, although they may be part of a larger laboratory network or system. A laboratory may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation. (用例) Medical laboratory services are essential to patient care and therefore should be available to meet the needs of all patients and clinical personnel responsible for human health care.

148	medical record	診療録		(用例) request forms (including the patient chart or medical record only if used as the request form) If data in other computer systems can be accessed through the laboratory information system (LIS) (e.g., pharmacy or medical records), there should be appropriate computer security measures to prevent unauthorized access to these data through the LIS
149	monitoring	モニタリング		(定義) process of constant evaluation of a state or condition (用例) There are two types of monitoring, that is, the results of measurements are validated against a defined limit, or the magnitude of a change in analyte concentration is used for decisions.
150	monoclonal antibody	モノクローナル抗体		(定義) Antibody capable of reacting specifically with a single epitope of a certain immunogenic substance. (用例) Details of procedure used by manufacturer to test the reactivity of the antibody for flow cytometry: – – 6) Use an irrelevant FITC– (Fluorescein IsoThioCyanate) conjugated monoclonal antibody of the same isotype as a negative control.
151	natural sample	実試料		(用例) Spiking should only be allowed if the resulting sample mimics natural samples.
152	needle and holder assembly	針・持針器一式		(定義) device that is intended to be attached to an evacuated receptacle to enable venous puncture and subsequent blood collection to be performed
153	nomenclature	命名法		(用例) 4.5:2 Nomenclature; The names of chemical compounds, biological components, quantities, units and symbols used shall be in accordance with European or International Standards, if available, or the latest recommendations of the appropriate International organization(s) see [20].
154	nominal capacity	公称容量		(定義) volume of specimen and any additive with which the receptacle is intended to be filled
155	nominal fill line	公称充填標線		(定義) mark on a container, or its label, to indicate the nominal liquid capacity of a container, or filling capacity of a receptacle
156	nominal scale	名義尺度		(定義) scale with a set of possible values for a given kind-of-property that are each a word or symbol without any relation to magnitude (用例) Other properties than quantities may also be defined or reproduced by materials, but the assigned values cannot be expressed by a numerical value multiplied by a unit of measurement. Such values may be found on an ordinal scale or a nominal scale.

	語　彙	邦訳語	摘　要	定　義・用　例
157	non-conformity	不適合	JIS Q 9001	(定義) nonfulfilment of a requirement, ISO 8402:1994 (用例) Each episode of non-conformity is documented and recorded. These records shall be reviewed at regular specified intervals by laboratory management to detect trends and initiate preventive action.
158	normative reference	引用規格		(用例) Changes have been made to the title, scope, normative references, and annexes, and the structure of text has reverted to the November 2000 version of prEN ISO/DIS 15189 sent to ISO/TC 176 review.
159	ordinal scale	序数尺度		(定義) scale with an ordered set of possible values for a given kind-of-property that are each a word or symbol used for ranking according to magnitude, but where differences or ratios between values have no arithmetic meaning (用例) As accuracy of measurement is a "qualitative" concept, a value in the form of a product of a numerical value and a unit cannot be assigned, but ordinal scale values such as "poor' and "good" may be used.
160	ordinal value	定性値		(用例) Trueness of measurement cannot be given a numerical value in terms of the measurand, only ordinal values (e.g. poor, good).
161	outer container	外箱		(定義) material used in the packaging of the immediate container(s) of (an) IVD reagent(s) consisting of a single entity or an assembly of different or identical components (用例) The labels of the immediate container and the outer container shall be in accordance with EN 375. The product name on the label shall be in accordance with clause 4.
162	outlier	外れ値		(用例) The data should be scrutinized for consistency and outliers in accordance with ISO 5725-2 and further evaluated in accordance with ISO/IEC Guide 35, or alternatively non-parametric approaches may be used.
163	package insert	添付文書		(定義) any labelling which pertains to the reagent system and the quality control material that is not attached to any part of the package (用例) Instructions for use include package insert sheets and user manuals.

164	pathogens	病原体		(定義) Risk Group 1 (low individual and community risk); This group includes those microorganisms, bacteria, fungi, viruses and parasites, which are unlikely to cause disease in healthy workers or animals. Risk Group 2 (moderate individual risk, limited community risk) A pathogen that can cause human or animal disease but under normal circumstances, is unlikely to be a serious hazard to healthy laboratory workers, the community, livestock, or the environment. Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available and the risk of spread is limited. Risk Group 3 (high individual risk, low community risk) A pathogen that usually causes serious human or animal disease, or which can result in serious economic consequences but does not ordinarily spread by casual contact from one individual to another, or that can be treated by antimicrobial or antiparasitic agents. Risk Group 4 (high individual risk, high community risk) A pathogen that usually produces very serious human animal disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly, or casual contact. (用例) All laboratories working with viable pathogens shall have design characteristics appropriate to the containment of microorganisms of moderate individual risk to limit community risk.
165	performance claim	性能仕様		(定義) every specification in regard to the performance of an in vitro diagnostic medical device laid down in the information supplied by the manufacturer
166	performance evaluation	性能評価		(定義) investigation of the performance of an in vitro diagnostic medical device based upon data already available, scientific literature and/or performance evaluation studies (用例) The purpose of the user performance evaluation is to demonstrate that users are able to operate the blood glucose monitoring system given only the routinely provided instructions and training materials.
167	performance evaluation study	性能評価調査		(定義) investigation of an in vitro diagnostic medical device intended to validate the performance claims under the anticipated conditions of use
168	performance goal	性能目標		(定義) the analytical performance (i.e., bias, imprecision, nonspecificity) of an assay desired for a particular clinical application (用例) The document addresses analytical performance goals for laboratory procedures in relationship to medical requirements.

	語　彙	邦訳語	摘　要	定　義・用　例
169	performance of an in vitro diagnostic medical device	体外診断用医薬品・医療機器の性能		(定義) set of properties of an in vitro diagnostic medical device related to its suitability for the intended purpose
170	performance specification	性能仕様		(用例) Performance specifications for each procedure used in an examination shall relate to the intended use of the procedure.
171	performance study records	性能調査記録		(定義) documentation of the experimental steps during the performance evaluation study and results obtained
172	personal protective equipment	個人用防具		(定義) material, including clothing, used to prevent contamination of a person by chemical or biological matter (用例) Personal protective equipment, including thermal protective gloves and appropriate clothing, shall be provided to allow for personnel safety and comfort.
173	polyclonal antibody	ポリクローナル抗体		(定義) Mixture of antibodies capable of reacting specifically with a certain immunogenic substance.
174	population	母集団		(用例) If the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population, then an investigation shall be undertaken, followed, if necessary, by corrective action.
175	post-analytical phase	分析後工程		(定義) all processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting of results, transmission of the results, and storage of samples of the examinations
176	post-examination procedure	検査後手順		(用例) External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and that check the entire examination process including pre- and post-examination procedures.
177	post-examination process	検査後工程		(定義) all processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting of results, transmission of the results, and storage of samples of the examinations
178	potentially infectious biological material	感染性生物試料		(定義) material which might contain infectious biological material albeit with a low probability
179	pre-analytical phase	分析前工程		(定義) steps starting in chronological order from the clinicians' request, including the examination requisition, preparation of the patient, collection of the primary sample, transportation to and within the laboratory and ending when the analytical examination procedure starts

180	precision	精密さ		(定義) the closeness of agreement between independent results obtained under stipulated conditions. (The numerical results are expressed as imprecision.) (用例) Precision of measurement cannot be given a numerical value in terms of the measurand, only descriptions such as 'sufficient' or 'insufficient' for a stated purpose.
181	prediction limits	予測限界		(用例) 7.7 The expected variability of comparison around the regression line (prediction limits) may be estimated at a given probability on the basis of the number of samples and the respective uncertainties of the two measurement procedures.
182	pre-examination procedure	検査前手順		(用例) External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and that check the entire examination process including pre- and post-examination procedures.
183	pre-examination process	検査前工程		(定義) steps starting in chronological order from the clinicians' request, including the examination requisition, preparation of the patient, collection of the primary sample, transportation to and within the laboratory and ending when the analytical examination procedure starts
184	preventive action	予防処置		(用例) When deficiencies or opportunities for improvement are noted, the laboratory shall undertake appropriate corrective or preventive actions, which shall be documented and carried out within an agreed-upon time.
185	preventive maintenance	予防保全		(用例) It shall also have a documented and recorded programme of preventive maintenance (cf. 4.2.5) that, at a minimum follows the manufacturer's recommendations.
186	primary container	一次容器		(用例) the storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working reagents
187	primary data	一次データ		(用例) 4.12.3 Validation of primary data: When the primary data are obtained, they shall be validated. Guidelines shall be given on how the operator may ensure that the equipment functions properly and that ambient conditions are satisfactory, and how values measured on calibrators, samples, and blanks as appropriate shall lie within stipulated intervals.

	語　　彙	邦訳語	摘　　要	定　　義・用　　例
188	primary measurement standard	一次測定標準		(定義) standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity (用例) The series of measurement standards defined in VIM is based on the needs of calibration hierarchies for quantities. In physics, such as a length, a time, a temperature, a pressure, an electrical potential difference (voltage), a volume, and an absorbance, and comprises – primary measurement standard, – – –
189	primary pack	一次パック		(定義) smallest pack of receptacles
190	primary reference material	一次標準物質		(定義) reference material having the highest metrological qualities and whose value is determined by means of a primary reference measurement procedure (用例) The assigned value of such a reference material, even when it is highly purified, is related to a dedicated biological measurement procedure without traceability to SI units. Such a material, therefore, cannot be called a primary reference material
191	primary reference measurement procedure	一次基準測定操作法		(定義) reference measurement procedure having the highest metrological qualities, whose operation can be completely described and understood, for which a complete uncertainty statement can be written down in terms of SI units, and where results are, therefore, accepted without reference to a measurement standard of the quantity being measured (用例) A primary reference measurement procedure and one or more (certified) primary reference materials (used as calibrators) are available. These levels exist for approximately 25 to 30 types of quantity having well defined components, e.g. some electrolytes, metabolites, steroid hormones, and some thyroid hormones.
192	primary sample	一次試料		(定義) Collection of one or more parts initially taken from a system and intended to provide information about the system or to serve as a basis for a decision about the system (用例) Laboratory resources shall be maintained in a functional and reliable condition. Similar provisions should be made for primary sample collection and examinations at sites other than the permanent laboratory facility.

193	primary standard	一次標準		(定義) standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity (用例) A secondary standard means the standard whose value is assigned by comparison with a primary standard of the same quantity.
194	principle of measurement	測定原理		(用例) If relevant for comparability, comparative data shall be given on results of measurements on various types of sample to which the reference measurement procedure is claimed to apply with the procedure presented and with alternative measurement procedures differing in principle of measurement, method of measurement, or details of measurement procedure.
195	professional use	専門家用		(定義) use by personnel who have received special education and training with regard to procedures utilizing in vitro diagnostic medical devices (用例) This standard applies to all IVD medical devices intended for professional use.
196	proficiency testing	技能試験	JIS Q 0043	(定義) determination of laboratory measurement performance by means of interlaboratory measurement comparisons (用例) The systems for the surveillance of medical laboratory performance from an external source are known as external quality assessment schemes (EQAS) in Europe and proficiency testing (PT) in the USA (26).
197	quality	質		(定義) totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs
198	quality assurance	質保証		(定義) all the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality (用例) Personnel shall have training specifically in quality assurance and quality management for services offered.
199	quality control material	品質管理物質、精度管理物質		(定義) a substance, material, or article intended by its manufacturer to verify performance characteristics of a blood glucose monitoring system in conjunction with its use (用例) Equilibrate the blood glucose meter to 23 o C ± 2 o C. Run ten replicate samples, using the quality control material provided by the manufacturer.

	語　彙	邦訳語	摘　要	定　義・用　例
200	quality control range	品質管理許容範囲、精度管理許容範囲		(定義) the range of acceptable values (i.e., statistically justified) specified by the manufacturer, for results obtained using the quality control material (用例) If eight or fewer replicate results fall within the specified quality control range, the blood glucose meter has failed the vibration test.
201	quality management	品質マネジメント	JIS Q 9000	(用例) The laboratory management shall have responsibility for the design, implementation, maintenance, and improvement of the quality management system
202	quality manager	品質管理者		(用例) appointment of a quality manager (however named) with delegated responsibility and authority to oversee compliance with the requirements of the quality management system are followed and that the quality manual is kept up to date.
203	quality manual	品質マニュアル		(用例) Policies and objectives of the quality management system shall be defined in a quality policy statement under the authority of the laboratory director and documented in a quality manual.
204	quality policy	品質方針	JIS Q 9000	(用例) Policies and objectives of the quality management system shall be defined in a quality policy statement under the authority of the laboratory director and documented in a quality manual.
205	quality system	品質システム		(用例) The main elements of the quality system should normally be subject to internal audit once every twelve months.
206	quantity	量		(定義) attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively (用例) Before a traceability chain is established, the quantity (measurand) shall be defined with reference to the intended use of the result in medical decisions.
207	ratio scale	比率目盛		(用例) The type of scale on which the value of the quantity is measured shall be specified, that is whether it is a nominal, ordinal, difference, or ratio scale.
208	reagent blank	試薬盲検		(用例) The preparation of blank analytical portions of analytical sample blank and analytical reagent blank shall be detailed where applicable.
209	reagent system	試薬システム		(定義) the part of the in vitro diagnostic medical device that produces a signal via a chemical, or electrochemical reaction, that allows the analyte glucose to be detected and its concentration measured in a sample (用例) The reagent system units shall be taken from the same vial / package for each meter.

210	real-time stability testing	実安定性試験		(定義) exposing the IVD reagent to the conditions anticipated by the manufacturer to which an IVD reagent is exposed during transportation, storage and use, and investigating robustness and stability under these conditions
211	receptacle	試料採取容器		(定義) vessel intended to contain a specimen, together with any receptacle accessory and additive, with closure in place
212	receptacle accessory	試料採取容器添加物		(定義) component inside the receptacle which that is intended by the manufacturer to assist in the collection or mixing, or separation, of the specimen
213	receptacle interior	試料採取容器内壁		(定義) inside surface of the container receptacle or closure and outside the surface of any receptacle accessory exposed to the specimen
214	reconstitution	再溶解		(用例) d) techniques for achieving thawing or reconstitution followed by mixing:
215	recovery measurement	回収試験		(用例) 4.14.8 Recovery measurement: Where possible, recovery measurements shall be made and the results stated.
216	reference material (RM)	標準物質(RM)		(定義) material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement procedure, or for assigning values to materials (用例) The objective of a chosen traceable calibration is to transfer the degree of trueness of a reference material, and/or reference measurement procedure, to a procedure that is of a lower metrological order, e.g. a routine procedure.
217	reference measurement laboratory (RML)	基準測定検査室(RML)		(定義) laboratory that performs reference measurement procedures and provides results with stated uncertainties (用例) The reference measurement laboratory should provide traceable values on reference materials supplied by customers to the highest available level of reference measurement procedures or reference materials.
218	reference measurement procedure	基準測定操作法		(定義) Thoroughly investigated measurement procedure shown to yield values having an uncertainty of measurement commensurate with its intended use, especially in assessing the trueness of other measurement procedures for the same quantity and in characterizing reference materials (用例) In many cases, at present, there is no traceability above the manufacturer's selected measurement procedure or the manufacturer's working calibrator. In such cases, trueness is referred to that level of the calibration hierarchy until an internationally agreed reference measurement procedure and/or calibrator becomes available.

	語彙	邦訳語	摘要	定義・用例
219	reference measurement standard	基準測定標準		(用例) The series of measurement standards defined in VIM is based on the needs of calibration hierarchies for quantities In physics, such as a length, a time, a temperature, a pressure, an electrical potential difference (voltage), a volume, and an absorbance, and comprises – – – – reference measurement standard,
220	reference measurement system	基準測定体系		(用例) Reference measurement systems are needed for producing useful and reliable results of measurement, whether in science, technology, or routine service so as to be comparable and ultimately traceable to measurement standards of the highest metrological level.
221	reference population	基準母集団		(用例) If the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population, then an investigation shall be undertaken, followed, if necessary, by corrective action.
222	reference stock	保存標準菌株		(定義) Lot of containers obtained in the laboratory by a single propagation from a reference strain or multiple containers from the same lot of a reference strain from a supplier.
223	reference strain	標準菌株		(定義) Microorganism defined to at least the genus and species level, catalogued and described according to its characteristics.
224	reference value	基準値		(用例) biological reference interval: reference value
225	referral laboratory	委託検査室		(定義) external laboratory to which a sample is submitted for a supplemental or confirmatory examination procedure and report (用例) When examination results from a referral laboratory need to be transcribed by the referring laboratory, procedures to verify the correctness of all transcriptions shall be in place.
226	referring laboratory	委託元検査室		(用例) The referring laboratory and not the referral laboratory shall report referral laboratory examination results and findings to the person making the request.
227	repeatability	併行精度、繰り返し精度	JIS Z 8402-1	(用例) 1. Scope: —— a) control materials that do not have an assigned value and are used only for assessing the precision of a measurement procedure, either its repeatability or reproducibility (precision control materials);
228	repeatability coefficient of variation	併行変動係数、繰り返し変動係数		(用例) 4.16.2 Statistics: – – – i) repeatability coefficient of variation;

229	repeatability limit	併行許容誤差、繰り返し許容誤差		(用例) 4.16.2 Statistics: – – – j) repeatability limit
230	repeatability standard deviation	併行標準偏差、繰り返し標準偏差	JIS Z 8402-1	(用例) 4.16.2 Statistics: – – – k) repeatability standard deviation
231	reproducibility coefficient of variation	室間再現変動係数		(用例) 4.16.2 Statistics: – – – l) reproducibility coefficient of variation
232	reproducibility limit	室間再現許容差		(用例) 4.16.2 Statistics: – – – m) reproducibility limit
233	reproducibility standard deviation	室間再現標準偏差	JIS Z 8402	(用例) 4.1413 Reproducibility standard deviation (Sr): The value of the reproducibility standard deviation shall be stated, together,, if possible, with its,, ,uncertainty of measurement. If the value varies with the value of the quantity, a table or function shall be given:
234	requirement	要求事項		(用例) In some cases, a reference measurement procedure should be given in the form of a (written) standard, namely when it is related to technical requirements
235	routine measurement procedure	日常測定操作法		(用例) A secondary calibrator can be, e.g., a material with a matrix resembling those of the samples of human origin to be measured by the end-users' routine measurement procedures.
236	routine method	日常検査法		(用例) 5.4 Scope – a) current reference measurement procedure(s) or current generally-used routine methods of measurement or measurement procedures for which the reference material is produced;
237	safety hood	安全フード		(定義) covering over a medical laboratory device to reduce risk to a laboratory worker (用例) Venting of biological safety cabinets, chemical safety hoods, and cabinets shall, be appropriate to the microbiological and/or chemical risk and be consistent with safety requirements.
238	sample	標本 (統計)	検査材料の場合は「試料」を用いる	(定義) one or more units of product, either components or finished devices, drawn from a batch, the units of the sample being selected without regard to their quality (用例) test of one or more samples of equipment (or parts of equipment) made to a particular design, to show that the design and construction meet one or more requirements of the applicable standard
239	sample blank	試料盲検		(用例) The preparation of blank analytical portions of analytical sample blank and analytical reagent blank shall be detailed where applicable.

	語　彙	邦訳語	摘　要	定　義・用　例
240	sample size	標本数　(統計)	検査材料の場合は「試料数」を用いる	(定義) number of units of product in the sample (用例) Study designs, statistical analysis methods and acceptance criteria shall be established prior to data collection. Statistical methods, simulation models and sample size calculations shall be justified.
241	sampling inspection	抜き取り検査		(定義) process of inspecting a portion of the units of product that make up a batch (i.e. the sample) for the purpose of accepting or rejecting the entire batch, as prescribed in the associated (pre-established) sampling plan
242	sampling plan	標本抽出計画		(定義) specific plan which indicates the number of units of product (either components or finished devices) from each batch which are to be drawn for inspection and the associated criteria for determining the acceptability of the batch
243	sampling strategy	標本抽出方策		(定義) established method for obtaining an adequate sample
244	sanitation	消毒		(定義) process to reduce the presence of most pathogenic bacteria
245	scope	適用範囲		(用例) 共通タイトル
246	screening	スクリーニング		(定義) mass examination of an overtly healthy population to detect the presence of disease (用例) For the purpose of this document, screening is defined as the identification of unrecognized disease or defect in an apparently healthy population.
247	second opinion	セカンドオピニオン		(用例) The laboratory shall have an effective, documented procedure for evaluating and selecting referral laboratories as well as consultants who are to provide second opinions for histopathology, cytology, and related disciplines.
248	secondary measurement standard	二次測定標準		(定義) standard whose value is assigned by comparison with a primary standard of the same quantity (用例) The series of measurement standards defined in VIM is based on the needs of calibration hierarchies for quantities. In physics, such as a length, a time, a temperature, a pressure, an electrical potential difference (voltage), a volume, and an absorbance, and comprises – secondary measurement standard, – – –
249	secondary standard	二次標準		(定義) standard whose value is assigned by comparison with a primary standard of the same quantity (用例) A secondary standard means the standard whose value is assigned by comparison with a primary standard of the same quantity.

250	self-testing	自己測定		(定義) use in the home or similar environments by a lay person who will relate the result of the test to him- or herself
251	shelf life	有効期間		(定義) period until expiry date
252	specimen	一次試料		(定義) collection of one or more parts initially taken from a system
253	splashguard	飛散防具		(定義) device used to prevent personal contamination by a liquid (用例) Splashguards or similar devices shall be available for use when there is the potential for splashing of samples or reagents to occur.
254	starting material	初期材料		(用例) The origin of the starting material shall be stated in accordance with the terms given in 4.2.5.
255	statistical evaluation	統計学的評価		(定義) a method the objective of which is to measure the deviation from the assigned value in a manner that allows comparison with performance criteria (用例) A statistical evaluation of the data collected during the study shall be made. The method of evaluation shall be described.
256	sterilization	滅菌		(定義) complete elimination of rendering nonviable of all organisms, including pores (用例) Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabelling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions."
257	stock culture	標準保存株培養		(定義) Subculture(s) of a reference stock.
258	stock solution of stain	保存用染色液		(定義) Stable defined solution of one or more dyes at a higher concentration than that employed for staining.
259	storage life	保存期間		(用例) For reference materials of higher order, a stability allowing storage life from 8 to 10 years of use is a relevant aim. It is often possible to estimate how the decomposition will take place with time by exposing samples for relatively short periods (e.g. several weeks) to a range of temperatures, including some at which deterioration will occur more rapidly than at the proposed storage temperature.
260	subsample	分取試料		(用例) In some countries, the term specimen is used for primary sample (or a subsample of it) which is the sample prepared for sending to or as received by the laboratory and intended for examination.

	語　彙	邦訳語	摘　要	定　義・用　例
261	survey sample	調査試料		(定義) a sample sent to multiple laboratories for measurement or identification of selected analytes, where the result of such measurement or identification are returned to the EQAS organization for independent verification of each participant's technical competence
262	system	系、システム		(用例) In some cases, the information provided also applies to a larger system or a set of systems of which the sampled system is an element.
263	system analytical error	測定系の分析誤差		(定義) the range that encompass 95% of the differences between the results of the blood glucose monitoring system and the comparative method (manufacturer's standing measurement method) results. The comparative method must be clearly identified by the manufacturer and traceable to glucose reference method.
264	systematic error	系統誤差		(用例) performance specifications (e.g., linearity, precision, accuracy as expressed as standard uncertainty of measurement, detection limits, measuring interval, systematic error, analytical sensitivity, and analytical specificity);
265	test	検査		(定義) reportable interval of patient test results (用例) The laboratory director or designees for each task should have the appropriate training and background to be able to discharge the following responsibilities: a) provide advice to requesters about the choice of tests, the use of the laboratory service, and the interpretation of laboratory data; ——
266	testing	検査		(定義) The performance characteristics related to system accuracy are based on the results of testing performed as described in Clause 7, stated in language that is likely to be understood by the intended user. (用例) The safety aspects shall be covered, e.g. the testing of material of human origin for hepatitis B virus surface antigen, hepatitis C virus antibody, HIV antibody, and other markers of infectiveness as stipulated by regulations on each donated portion.
267	traceability	トレーサビリティ	JIS Q 0030	(定義) property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties (用例) The manufacturer's standing measurement procedure shall be traceable to a glucose reference measurement procedure or reference material of higher order. A detailed description of the measurement procedure and its traceability shall be provided upon request.

268	traceability chain	トレーサビリティ連鎖		(用例) Depending upon availability of measurement procedures and calibrators, a traceability chain can stop at any level from the end-user's routine measurement procedure (j)) upwards.
269	transfer protocol	トランスファープロトコル		(定義) detailed description for assigning a value of a quantity to a reference material using a specified sequence of measurement procedures calibrated by higher-order reference materials for the same type of quantity (用例) A given measurement standard with its assigned value shall serve to calibrate the measurement standard at the next lower level by way of a measurement procedure as specified in a transfer protocol.
270	transferability	伝達性		(用例) The validation of a candidate reference measurement procedure by planned inter-laboratory studies is a powerful way of identifying some sources of error, estimating; performance characteristics, and of assessing transferability and robustness of the reference measurement procedure.
271	transportation	搬送		(用例) These services include arrangements for requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples with subsequent validation, interpretation, reporting, and advice, as well as safety and ethics of medical laboratory work.
272	trivial name	慣用名		(用例) If a trivial name of a reagent is used it shall be given in parentheses following the systematic name the first time the systematic name appears in the text.
273	true value	真値		(定義) value consistent with the definition of a given particular quantity (用例) The indefinite article "a", rather than the definite article "the", is used in conjunction with "true value" because there maybe many values consistent with the definition of a given particular quantity.
274	true value of a quantity	量の真値		(定義) value consistent with the definition of a given particular quantity
275	trueness	真度		(定義) the closeness of agreement between the average value obtained from a large series of test results and an accepted reference value [ISO 3534-1] (用例) The trueness of measurement of a value assigned to a defined quantity of a calibrator or trueness control material, depends on the metrological traceability of the value through an unbroken chain of alternating measurement procedures and measurement standards (calibrators), usually having successively decreasing un-certainties of measurement.

	語　彙	邦訳語	摘　要	定　義・用　例
276	trueness control material	真度用管理物質		(定義) reference material that is used to assess the bias of measurement of a measuring system (用例) Traceability of a value assigned to a trueness control material shall utilize the calibration hierarchy.
277	turnaround time	所要時間		(用例) The laboratory management, in consultation with the requesters, shall establish turnaround times for each of its examinations.
278	types of quantity	量の種類		(用例) 1) A primary reference measurement procedure and one or more (certified) primary reference materials (used as calibrators) are available. These levels exist for approximately 25 to 30 types of quantity having well defined components, e.g. some electrolytes, metabolites, steroid hormones, and some thyroid hormones.
279	uncertainty	不確かさ		(用例) The components of uncertainty are evaluated experimentally from statistical distributions (Type A) or evaluated from assumed probability distributions based on experience or other information (Type B). All components are expressed as standard uncertainties that are combined into one final expression.
280	uncertainty budget	不確かさの見積り		(用例) a combined uncertainty Uc obtained as the outcome of an uncertainty budget
281	uncertainty components	不確かさ成分		(用例) Uncertainty components which are of importance shall be taken into account.
282	uncertainty of measurement	測定の不確かさ		(定義) parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand (用例) The value assigned to a measurement standard at a given level shall be associated with an uncertainty of measurement that shall include inherited consecutive uncertainty contributions from measurement standards and measurement procedures at all higher levels of the calibration hierarchy.
283	user manual	ユーザーマニュアル		(定義) information supplied for use with an instrument containing instructions for the proper use and for the safe and correct operation, maintenance and basic troubleshooting of the instrument (用例) The blood glucose meter shall be defined by labels including, at a minimum, the following information: --- f) a reference to the user manual or instructions for use.

284	validation	妥当性確認		(定義) confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled [ISO 8402:1994, 2.18] (用例) The validation of the commutability of the pertinent calibrators and of the traceability of their assigned values shall not use the same set of native human samples.
285	value assignment	値付け		(用例) 5.9.5 Value assignment: The experimental plan and the reference measurement procedures used in assigning values shall be described (see also I SO/IEC Guide 35).
286	verification	検証		(定義) confirmation by examination and provision of objective evidence that specified requirements have been fulfilled (用例) Documentation of the supplier's conformance to its quality management system may also be used for verification.
287	visual inspection	目視検査		(定義) inspection by an observer with normal, or corrected-to-normal, vision without magnification, under a uniform illumination in the range from 300 lx to 750 lx
288	working culture	作業用培養物		(定義) Subculture of a stock culture.
289	working measurement standard	実用測定標準		(定義) standard that is used routinely to calibrate or check material measures, measuring instruments or reference materials (用例) The series of measurement standards defined in VIM is based on the needs of calibration hierarchies for quantities. In physics, such as a length, a time, a temperature, a pressure, an electrical potential difference (voltage), a volume, and an absorbance, and comprises – working measurement standard.
290	working standard	実用標準		(定義) standard that is used routinely to calibrate or check material measures, measuring instruments or reference material
291	workload	作業量		(用例) The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures, safety of personnel, and patient care services.

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