Work Instruction for Testing Scopes of Accreditation (including medical) and Flexible Scopes

The scope of accreditation is a formal document issued by PJLA to its accredited laboratories. It contains information for which accreditation has been granted in regard to the types of tests performed, techniques used, and detection limits.

It is the responsibility of the laboratory to prepare its proposed scope of accreditation before the initial assessment. The proposed scope of accreditation will be reviewed by the PJLA assessor onsite for accuracy and completeness. Once the assessor has agreed with the proposed scope of accreditation, both the laboratory and the assessor will sign the proposed scope and submit it to PJLA for review with the assessment package. Please note that the submitted scope of accreditation can be modified by PJLA after technical review of the assessment package. Once the accreditation is granted, PJLA will issue a final certificate. The final certificate will be made available to the public through the PJLA website.

The following information should be used to complete the scope of accreditation for the Application for Services and the certificate Supplement worksheet documents.

APPENDIX A

Certificate Required Fields/Format for Non-Medical Laboratories

Field of Test:

The entry in this field needs to represent the generic classification of the testing services provided by the laboratory. When completing this field, the entry needs to describe the discipline broadly. Appendix A of this work instruction includes a listing of appropriate fields to be used based on the types of testing that is being provided by the laboratory. Should you find that your testing areas do not fit into the fields listed below, please notify PJLA staff to assist you with completing this section of your scope of accreditation.

Testing Field:

1. Biological: Biological, microbiological and biochemical testing and measurement.
2. Chemical: Chemical analysis and detection including instrumental and automated methods.
3. Dimensional Inspection
4. Electrical: Tests of an electrical and electronic nature performed on instruments, equipment, appliances, components, and materials.
5. Environmental: Tests for constituents in various environmental media.
6. Mechanical: Tests, measurements, and evaluation of physical properties of materials, components, and assemblies.
7. Non-Destructive: Examination of materials, components, and assemblies to detect discontinuities without damaging the material, component, or assembly.

Items, Materials or Products Tested:

Define the products, materials or other items that you test using the technology defined in column three. For example: Metals, Waste Water, or Plastic Components.

Specific Tests or Properties Measured:

The entry in this field needs to represent the tests you are performing. This entry needs to be specific and fully describe the test or property so as to indicate the capabilities of the laboratory.

Specification, Standard Method or Technique Used:

Enter all of the test methods that are used when performing tests in the technologies related to the third column. The test method may be an internationally recognized test method such as ASTM, SAE or other accepted methods. This may also be a customer

specified method or internal method. Whichever method is stated on the scope, the laboratory is expected to have available the most current version of that method.

Range (Where Appropriate) and Detection Limit:

Provide the lower and upper boundaries for the range of the parameter. Beware of including a zero as the lower boundary, especially when a percent or multiplier is used

Detection limit for the product in the manner to be tested must be provided. Detection Limit can be expressed in quantitative or qualitative terms as necessary. The capabilities of the laboratory need to be clearly expressed in an easy to understand format.

The units, which define the measurement, must comply with acceptable units. Please refer to NIST SP 811 and Appendix B of this document regarding the use of SI units.

Format:

A separate line entry is needed for each parameter/discipline and/or each range listed for that parameter. For each line entry, a separate line must be used for each range.

The format of the example table must be followed. This includes font (Times New Roman), font size (10), column order and column headings, and placement of notes. Blank Boxes and boxes containing the phrase “N/A” will only be accepted for the range of the parameter and not the detection limit, where applicable.

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Environmental	Waste Water	Sodium Content	EPA 10528	0.001 mg/dl to 0.15 mg/dl 0.000012 mg/dl
Mechanical	Automotive Components	Chipping Resistance	SAE 4500A	± 5%

APPENDIX B

Certificate Required Fields/Format for Medical Laboratories

Discipline:

The Discipline describes the medical laboratory testing area for the activity.

Examples of possible disciplines:

Disciplines	Microbiology	Hematology	Radiobioassay	Chemistry
	Bacteriology	Immunohematology	Cytology	Endocrinology
	Mycology	ABO and Rh typing	Histocompatibility	Toxicology
	Mycobacteriology	Anatomic Pathology	Cytogenetics	Urinalysis
	Parasitology	Histopathology	Molecular Pathology	Immunology

Process of Examination:

The process of examination is the particular test or examination to be performed on the test sample. The examination could be performed by various methodologies or technologies. The Measurement Techniques/Instrument is where the specific method or technology can be entered to more narrowly define the test activity.

Example:

Discipline	Process of Examination	Test Sample	Property	Parameter/Range	Measurement Techniques / Instrument
Mycobacteriology	Acid Fast smear exam *Examination is staining a smear of concentrated sputum*	Concentrated sputum	Detection of acid fast bacilli	-	A/O Stain *This is a specific technique for acid fast staining. Another lab may use Kinyoun Stain.*

Test Sample:

Provide a description of the material being examined or tested. The specimen collected may be blood, however the material being tested in the serum of that blood. Describing the test sample as serum indicates how the blood specimen should be collected to

perform the test. This description may include additives necessary for preservation of a sample for testing. A test may permit the use of EDTA as an anticoagulant but may not be run if the anticoagulant is heparin. See examples in the table below

Property:

The property is what will be measured, detected, or identified by the examination or test, such as an analyte, pathogenic organism, mutation, gene, or antibody.

Parameter/Range:

This field is optional. The Parameter/Range describes the type of data generated by the test. This field may contain the detection or reporting range for a quantitative test for a particular analyte, such as a viral load test report. For qualitative examinations the field may convey that the test may be semi-quantitative scored as 1+ to 4+, or the test may detect only a presence or absence of a particular property. Some examination and test reporting formats are standard knowledge in the medical field so that the lab may not find value in providing an entry for this field.

Measurement Techniques/Instrument:

This is an optional field. If the Process of Examination field is sufficient to convey the test methodology, there may not be any added value to providing a particular methodology or testing system here. For those performing lab developed or branded test systems or assays, this field may be used to promote their method. For example, a genetic testing facility may examine samples using Next Generation Sequencing but have their own libraries or interpretative tools applied and branded for FDA approval. In that case, the lab may list the Process of Examination as Next Generation Sequencing and use their product name in the Measurement Techniques/Instrument field.

Discipline	Process of Examination	Test Sample	Property	Parameter/Range	Measurement Techniques / Instrument
Immunology	Serum Protein Immunology	Serum	CRP	-	-
Hematology	Blood Functional Test	Blood	HbA1c	4.5% to 10.0% NGSP	EIA (Hitachi 7050)
Microbiology	Urine Culture with Identification	Urine	Pathogens (E. coli)	Presence/Absence	VITEK

Biochemistry	Automated system	Serum	YGT	CV_A : 8.2%, B_A: 12.8%	IFCC Traceable Method (Hitachi 7050 Type)
Hematology	Blood Test	Blood	RBC	CV:4.1%	See-Through Method (Sysmex XN-550)

APPENDIX C

Guidelines for the use of SI units for the scope of accreditation

The General Conference on Weights and Measures established the International System of Units (SI). It is the modern metric system of measurement used throughout the world.

PJLA policy requires the use of SI units to be used for reporting results of measurements on scopes of accreditation. This policy calls for the use of NIST SP 811 for direct guidance on the use of symbols, numbers, and the use of the SI Units.

It is the responsibility of the client to be aware of the appropriateness of the SI unit on their scope of accreditation as applicable. In some cases, U.S. customary units may be more appropriate. The NIST SP 811 can be retrieved from www.nist.gov .

The following pages contain a small sampling of guidelines and examples contained in the NIST SP 811.

Rule:	**Example:**	**Instead Of:**
Only units of the SI and those recognized by the SI are used.	10 m 100 °C	10 ft. 100 °F
Abbreviations are avoided	S or second cm^3 or cubic centimeter	sec cc
ppm, ppb and ppt are avoided	2 ng/kg 1.1 nm/m	2 ppt 1.1 ppb
Unit symbols are not modified in order to provide information about the quantity.	$V_{max} = 1000$ V	$V = 1000\ V_{max}$
The symbol “%” can be used in place of the number 0.01	$x_\beta = 0.0038 = 0.38$ %	$x_\beta = 0.25$ percent
Quantities are to be defined so that they can be expressed solely in	The Ca content is 25 ng/L	25 ng Ca/L

acceptable units		
Unit and mathematical symbols and names are not mixed	m/s or meter per second	meter/s
Values for quantities are expressed in acceptable units using Arabic numerals and the SI symbols for units	The weight of the box was 35 kg.	The length of the box was thirty-five kilograms.
There is always a space between the quantity and the unit symbol, except when it is a plane angle	189 kg 25 °C 357 Ω 24° (plane angle)	189kg 25°C 357Ω 24 ° (plane angle)
A thin space is used to separate digits with more than four per side of a decimal point	123 586 257.004 1	123586257.0041 or 123,586,257.0041
Quantity equations are preferred to numerical value equations	l = vt	$\{l\}_m = 3.6^{-1}\{v\}_{km/h}\ \{t\}_s$
A quotient quantity is expressed using “divided by” instead of “per unit”	Pressure is force divided by area.	Pressure is force per unit area.

Rule:	Example:	Instead Of:
The terms Normality and Molarity, symbols N and M respectively are obsolete. The preferred name is amount of substance concentration of B.	A solution having an amount of substance concentration of $c[(1/2)H_2SO_4]$	A 0.5 N solution of H_2SO_4
Values of quantities are to be written so that it is clear to which unit symbols the numerical values of the quantities belong.	51 mm x 51 mm x 25 mm	51 x 51 x 25 mm
The word “to” is used to indicate a range of values instead of a dash.	0 V to 5 V	0 V – 5 V

1. The word “weight” is used with the intended meaning clear. In science and technology, weight is defined as a force, for which the SI unit is the Newton. In commerce and everyday use, weight is used as a synonym for mass, for which the SI unit is the kilogram.
2. Standardized quantity symbols given in the ISO 31 series are used. Similarly, standardized mathematical signs and symbols such as those given is ISO 31-11 are used.

Appendix D

Guidelines for developing and using a flexible scope

PJLA follows ILAC-G18:04/2010 *Guidelines for the Formulation of Scopes of Accreditation for Laboratories* as it applies to flexible scopes of accreditation. When a laboratory is granted a flexible scope, it is allowed to include additional activities in its scope of accreditation on the basis of its own validations without evaluation prior to operation of the activity. The possibility of introducing new, modified or laboratory developed methods under a flexible scope does not include introduction of new measurement principles of testing, calibration or examination not previously covered by the scope of accreditation. A flexible scope can be established based on degrees of freedom for flexibility such as:

- Flexibility concerning object/matrix/sample
    - This means flexibility that allows for changes with respect to various products (e.g. change in matrices) within a product area. For example this covers electrothermal/graphite tube atomic absorption spectroscopy which is extended from determination of cadmium in fruit, jams and other fruit products for the determination of cadmium in cereals and bakery products. Another example is mechanical testing of various components (e.g. wheels, suspensions) for automotive applications.
- Flexibility concerning parameters/components/analytes
    - This means flexibility that allows for changes with respect to parameters. An example is the extension of cadmium determination in food to other trace metals by electrothermal/graphite tube atomic absorption spectroscopy.
- Flexibility concerning the performance of the method
    - This means flexibility that allows for changes in the performance of the method for a given specimen type and a given parameter. This includes for example, the modification of measuring range and uncertainty.
- Flexibility concerning the method
    - This means flexibility that allows adoption of methods that are equivalent to methods already covered by accreditation. An example is the extension of in-plane displacement field measurement by 2D- ESPI (electronic speckle pattern interferometry) to three dimensional distribution of the displacement by 3D-ESPI.

Laboratories receiving this type of accreditation are not granted for a specific measurement procedure and limits of the flexibility are clearly set. A flexible scope and a fixed scope can be separately described or combined within one accreditation whatever is the most convenient or informative. In all cases, the laboratory must retain an updated list of all methods for which accreditation is held, including newly modified, introduced or developed methods for review by PJLA.

Laboratories maintaining a flexible scope of accreditation must have fully documented procedures for the validation of method modifications (including modifications of parameters and matrices) and for the verification of additional methods to be covered under the flexible accreditation scope.

This means the laboratory must provide documented evidence to PJLA that the laboratory has complied with the requirements of ISO/IEC 17025 with regard to validation of methods. The appropriateness and robustness of the laboratory's validation procedures will be assessed by PJLA prior to granting accreditation for a flexible scope. Complete records of validation and verification of methods and the data obtained must be retained and made available for review at initial assessment, surveillance visits, and reassessments or on request. Records of modifications to test methods and development activities, including all the underlying results and other relevant data, must be controlled and maintained.

References:

-ILAC G18:04/2010 Guidelines for the Formulation of Scopes of Accreditation for Laboratories

-ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

-NIST Special Publication 811 2008 Edition-Guide for the Use of the International System of Units (SI)

-ISO 15189:2012 Medical laboratories — Particular requirements for quality and competence