KAN-TN-LM 04

KAN TECHNICAL NOTES ON MEDICAL LABORATORY IN THE FIELD OF HEMATOLOGY

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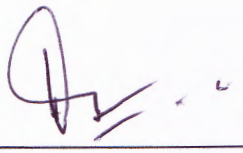

Quality Manager of National Accreditation Committee of Indonesia (KAN)

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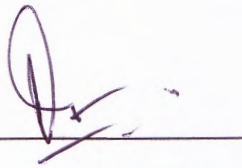

Director of National Accreditation Committee of Indonesia (KAN)

LIST OF AMENDMENT

No.	Date	Part number revised	Brief description of changes	Part revision number
1	January 2008	Clause 2	Adding clause 2(a) – Personnel	1
		Clause 3	Adding clause 3 (a) – (f)	
2	7 April 2016	Identification document KAN-R-LM 01	Identification document changed to KAN-TN-LM 01	2
3	7 April 2016	Clause 1	Replace SNI ISO 15189:2009 into SNI ISO 15189:2012	2
4	7 April 2016	Clause 1 d.	Delete "..red blood cells, leukocyte counts, serum, hemoglobin level, microglobulin…"	1
5	7 April 2016	Clause 2 d.	Delete "..a pharmacist or a veterinarian.."	1
6	7 April 2016	Clause 5 a. ix	Replace "…shall verification.." into "..should be verified.."	1
7	7 April 2016	Clause 5 a. xiv	Replace "..are.."into "..should be.."	1
8	7 April 2016	Clause 5 a. xiv ii	Replace "..producing..", "..purchasing…", and "..shall check.." into "..is produced..", "..purchased..", and "..shall be checked.."	1
9	7 April 2016	Bibliography	Delete EA-4/10 G Withdrawn May 2014	1

KAN TECHNICAL NOTES ON MEDICAL LABORATORY IN THE FIELD OF HEMATOLOGY

1 INTRODUCTION

a This technical notes are an interpretation of the general requirements of SNI ISO 15189:2012

b This accreditation technical notes are applicable to Medical Testing" in field the of examinations of hematology, testing technical, type of test, and or specific examination in hematology area, as extra information to the already generally stated requirements in each of the clauses SNI ISO 15189:2012.

c Hematology is the branch of physiology, clinical pathology, clinical laboratory, internal medicine, and pediatrics that is concerned with the study of blood, the blood-forming organs, and blood diseases. Hematology includes the examination of etiology, diagnosis, treatment, prognosis, and prevention of blood diseases. Blood diseases affect the production of blood and its components, such as blood cells, hemoglobin, blood proteins, the mechanism of coagulation, etc.

d Hematology examination is taken to include examinations of complete blood counts (red blood cells, leukocyte, platelet, hemoglobin level, red cell indices, leukocyte differential count, erythrocyte sedimentation rate / ESR), blood films morphology, reticulocyte counts, bone marrow evaluation, fetal / abnormal Hb, red cell enzyme, haemolysis, hemostasis, cryoglobulins / cryofibrinogen, plasma / whole blood viscosity, immunophenotyping, heterofil antibody / infectious mononucleosis, in vivo radioisotopes hematological studies, malarial / other parasites, platelet function, coagulation test (prothrombin time / PT and partial thromboplastin time / PTT, fibrinogen) and related tests.

2 PERSONNEL

a The laboratory analyst has been working in hematology examination areas of a medical laboratory for at least two years.

b Technical manager, laboratory supervisors and laboratory analysts shall possess a basic education in medical technologist, hematology, biological analysis, health analysis vocation or a related science.

c Consultations and clinical interpretations of examination test results shall be provided by a qualified hematologist.

d Qualified hematologist is a physician, responsible for the interpretation data derived from body fluids such as blood, urine, and tissue aspirates.

e The laboratory shall be directed by persons having executive responsibility & competence to assume responsibility for the services of hematology examination.

f Laboratory management shall ensure that:

i appropriate numbers of laboratory personnel, with the required education & training, to meet the demands of the service to customers,

ii laboratory personnesl have the knowledge, skills, and abilities based on education, experience, demonstrated skills, and training to perform their duties,

iii full educational and professional records of all technical staffs are available to confirm their competence in hematology testing.

g The laboratory management shall involve in the continuous education of all staffs.

h Laboratory shall establish and define an internal training program and ensure the competency of laboratory personnels.

i Performance of laboratory personnels shall be evaluated regularly to ensure their continuing competence.

j Laboratory shall have a training procedure that used to ensure that training has taken place with each employee for procedures and methods that the employee performs. The procedure applies to on-the-job training, in-house training and new-hire training.

k The training procedure is applicable to new employees, for the introduction of new procedures and methods, for re-training of employees, and for re-verification of employee performance.

l The laboratory shall maintain an up-to-date record of the training that each member of staff has received

3 EXAMINATION METHODS

a The examination method is adequately documented based on the latest valid edition of a published reference method, including:

i title and method number,

ii scope and field of application,

iii number of revision,

iv page numbering, total number of pages,

v references,

vi principles and definitions,

vii reagents and materials,

viii apparatus,

ix analytical methodology,

x expression of results,

xi performance criteria,

xii storage and shelf-life,

xiii quality control,

xiv reporting criteria,

xv issuing authority.

b Laboratory shall have:

i written procedures for the proper collection and specimen handling and storage conditions,

ii procedures to verify sample identity and integrity,

iii Policy and specification for the maximum interval during which a specimen may be used for the specified examination,

iv clinical information and diagnosis provided on the request form,

v procedures to verify sample identity and integrity,

vi documentations detailing methods for patient identification, specimen labeling, specimen preservation and storage before testing,

vii written criteria, procedures and records for specimen rejection,

viii secondary samples that traceable to the primary sample.

c Supporting work instructions shall available to

i work instructions for sample disposal,

ii work instructions for disinfection / sterilization and disposal of biohazardous material,

iii work instructions for glassware cleaning,

iv work instructions for equipment instruction manuals,

v Work instructions for computer software related data entry and approval.

4 EQUIPMENT AND MEASUREMENT TRACEABILITY

a Laboratory shall have:

i list of the major equipment such as spectrophotometer, hematology cell counter, stainer, analyzers for coagulation & electrophoresis, pH meter, automated system for reticulocyte counts, automated haematology cell counter system, including identification, date received, manufacturer, maintenance service,

ii procedure specifies the schedule and requirements for maintenance, performance, calibration, and verification of laboratory testing equipment that meet the criteria of the maintenance and calibration parameters needed to achieve the accuracy of instruments used for analytical testing,

iii equipment records containing description of the instrument, critical accessories and software, manufacturer's name, type identification and serial number; laboratory number; installation qualification (IQ) and operational qualification (OQ) records obtained from the installer or manufacturer; and other related material such as instrument

service and repair, warranty information, service contract conditions and specifications,

iv laboratory shall have operating instructions for each instrument, including starting and shutting down the instrument,

v safety cabinet shall have documented protocol and record of decontamination,

vi verification at regular intervals of the minimum/maximum time for lysing from *Cell Counting, Cell Size Measurement and Hemoglobin Determination*,

vii background counts preformed on the diluents and lysing agent to check for contamination,

viii automatic pipettes is there an initial verification of volume delivered checked,

ix counting chambers for blood cells for examination of manual platelet, red and white blood cell count should be verified regularly,

x there should be regular checks to ensure that the equipment is performing within the specifications,

xi equipment that is not operating properly is clearly marked to show that it is out of service,

xii when an instrument is discovered to be improperly operating, it is tagged and taken out of service. Equipment is not returned to service until performance checks and verification have been performed and documented,

xiii each instrument has an established schedule specifying performance checks, including the testing frequency and acceptable performance specifications. These performance checks ensure the instrument is operating properly and consistently prior to analysis,

xiv all instruments required for the routine examination in hematology field should be available,

xv regularly scheduled maintenance program for each piece of equipment, where appropriate and records of service where service was required,

xvi distilled water that is produced in-house and or purchased from external supplier and used to make media or reagents in hematology examinations shall be checked the conductivity periodically,

b Laboratory shall have arrangement for avoidance of cross-contamination arising from equipment, such as:

a) disposable equipment should be clean and sterile when appropriate,

b) re-used glassware should be properly cleaned and sterilized when appropriate.

c Where centrifuges are used in examination procedures, an assessment should be made of the criticality of the centrifugal force. Where it is critical, the centrifuge will require calibration.

5 REAGENTS AND REFERENCE CULTURES

a Laboratory shall have sufficient & appropriate quantities of reagents /media / commercial kits available to carry out the volume of work following the required examination methods.

b Raw materials (dehydrated formulations and individual constituents) should be stored under appropriate conditions, e.g. cool, dry and dark.

c All containers, especially those for dehydrated media, should be sealed tightly.

d Stored reagents, reference materials and supplies shall be under the appropriate conditions and in a secure manner to ensure the separation of incompatible materials

e Solutions of reagent, standard and any other such as mobile phase properly labeled with solution name, concentration, date of preparation, expiration date, and identity of person who prepared.

f Disposed of reagents and standards solutions appropriately followed to National and or local regulation

g Distilled or de-ionized water systems are monitored for conductivity, bacterial content, and total chlorine periodically. Heavy metals analysis, water quality test and use test are performed annually on the water systems.

h Laboratories shall ensure that all reagents including stock solutions, media, diluents, and other suspending fluids are adequately labeled to indicate, as appropriate, identity, concentration, storage conditions, preparation date, and validated expiry date and / or recommended storage periods.

6 ASSURING THE QUALITY OF EXAMINATION RESULTS

a Laboratory quality control is an essential aspect of ensuring that data released is fit for the purpose determined by the quality objectives.

b Approach of quality control is the principal recourse available for ensuring that only quality data is released.

c The principle of the laboratory quality control program is its internal quality control to monitoring of analytical performance, and its external quality control based on the laboratory's performance in proficiency testing programs.

d Laboratory management is responsible for establishing a laboratory quality control program and ensures that quality control is performed and reviewed of quality control data for acceptability.

e Analysts are responsible for conducting quality control analyses in accordance with the laboratory quality control program.

f Internal quality control is used to measure accuracy, precision, contamination, and matrix effects. The laboratory determines, where feasible, the accuracy and precision of all analyses performed.

g Accuracy and precision control charts are used to determine if the measurement system process is in control and whether the results generated by the measurement system are acceptable.

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