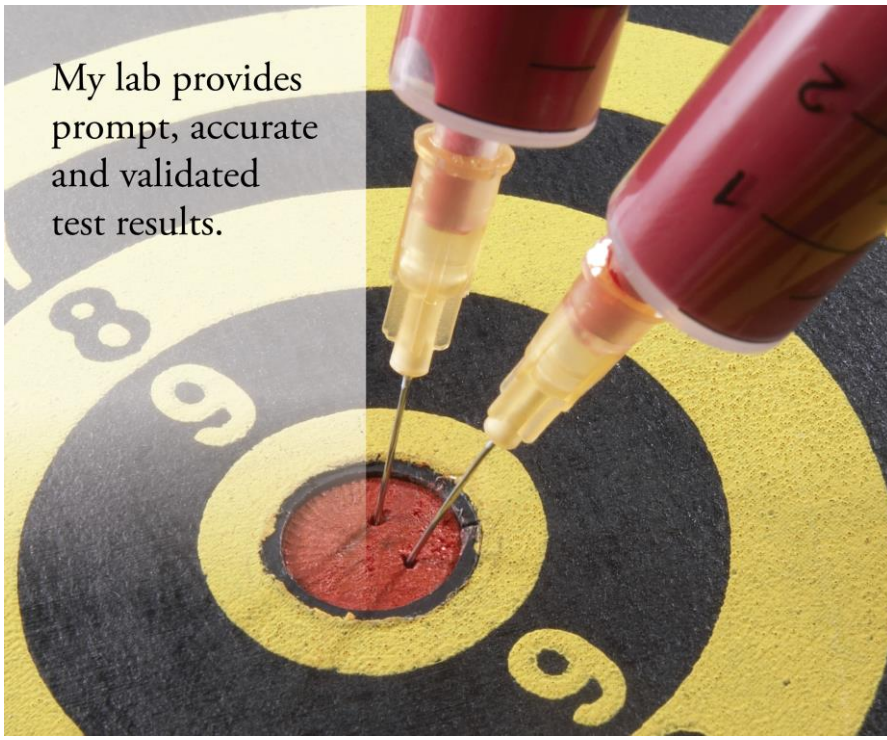
MODULE 8

Laboratory Testing



SLMTA Participant's Manual

TABLE OF CONTENTS

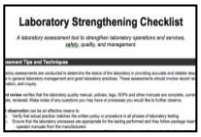
NOTE: Print this document single-sided and in color if possible.

ACTIVITY SUMMARY SHEET

ACTIVITY Validation of Test Results — Module 8

PURPOSE:

The total testing process can be divided into three phases, the pre-analytical phase, the analytical phase, and the post analytical phase. A problem or error in any of the three phases can invalidate the results of the entire testing process. In this activity, participants identify the potential sources of errors or problems and create a checklist to verify patient results before their release.

This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	6.4 Validate new equipment, reagents, and supplies 7.3 Enforce good specimen handling and processing practices 8.4 Validate assigned tests and specific abnormal results
Checklist Items 	1.2 Laboratory Quality Manual Is there a current laboratory quality manual, composed of the quality management system's policies and has the manual content been communicated to, understood and implemented by all staff? 1.5 Laboratory Policies and Standard Operating Procedures Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Purchasing and Inventory Control; Pre-examination Processes; Validation and Verification of examination procedures / Equipment; Quality Control and Quality Assurance) 6.1 Internal Audits Are internal audits conducted at intervals as defined in the quality manual and do these audits address areas important to patient care? 7.10 Product Expiration Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiration or within stability? 8.1 Information for Patients and Users Are guidelines for patient identification, specimen collection (including client safety), labelling, and transport readily available to persons responsible for primary sample collection? 8.2 Does the laboratory adequately collect information needed for examination performance? 8.3 Are adequate sample receiving procedures in place? 8.4 Pre-examination Handling, Preparation and Storage Where testing does not occur immediately upon arrival in the laboratory, are specimens stored appropriately prior to testing? 8.7 Documentation of Examination Procedures Are examination procedures documented in a language commonly understood by all staff and available in appropriate locations? 8.8 Reagents Acceptance Testing Is each new reagent preparation, new lot number, new shipment of reagents or consumables verified before use and documented? 8.9 Quality Control Is internal quality control performed, documented, and verified for all tests/procedures before releasing patient results? 8.12 Are environmental conditions checked and reviewed accurately? 9.1 Test Result Reporting System Are test results legible, technically verified by an authorized person, and confirmed against patient identity? 9.2 Testing Personnel Are testing personnel identified on the result report or other records (manual or electronic)? 9.3 Report Content 9.8 Test Result Are test results validated, interpreted and released by appropriately-authorized personnel? 10.3 Is corrective action performed and documented for non-conforming work?

KEY MESSAGES

- The assurance of quality laboratory results relies on a commitment to assess all aspects of the total testing process.
- A problem or error in any of the three phases can invalidate the results of the entire testing process.
- For a QA program to be effective, the necessary policies and procedures must be developed and available to staff members.

Can you:

- Recognize that a problem or error in any of the three phases can invalidate the results of the whole testing process?
- Identify potential pitfalls at each phase of the total testing process?
- Create a checklist to verify areas before patient results are released?

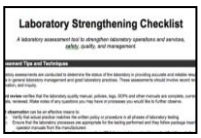
SELF-ASSESSMENT

ACTIVITY SUMMARY SHEET

ACTIVITY Is the Test Report Ready To Be Released? Module 8

PURPOSE:

Test result reports should be complete, accurate, legible, and clinically valid. In this activity, participants cross-check a test report to identify errors and omissions that must be resolved before the report is released.

This activity supports the following laboratory management tasks and SLIPTA checklist items	
Management Tasks 	8.1 Monitor testing to ensure SOPs are followed and tests are performed and reported properly and promptly 8.2 Cross-check test reports against test request to ensure completion of all tests 8.3 Review test records and findings promptly to ensure accuracy and timely release of test results 8.4 Validate assigned tests and specific abnormal results 9.1 Aggregate and report all test findings for each patient
Checklist Items 	1.5 Laboratory Policies and Standard Operating Procedures Are policies and/or standard operating procedures (SOPs) for laboratory functions, technical and managerial procedures current, available and approved by authorized personnel? (Identification and Control of Nonconformities; Authorization; Reporting and Release of Results) 9.1 Test Result Reporting System Are test results legible, technically verified by an authorized person, and confirmed against patient identity? 9.2 Testing Personnel Are testing personnel identified on the result report or other records (manual or electronic)? 9.3 Report Content 9.4 Analytic System/Method Tracing When more than one instrument is in use for the same test, are test results traceable to the equipment used for testing? 9.8 Test Result Are test results validated, interpreted and released by appropriately-authorized personnel? 10.3 Is corrective action performed and documented for non-conforming work?

KEY MESSAGES

- A cross-check provides a quality step to review accuracy and reliability of results prior to release.
- Each test request should have a corresponding result that is accurate and clinically meaningful.
- Laboratory errors and omissions are best handled prior to their release from the laboratory. However the most efficient way to handle errors is to prevent their initial occurrence.

Can you:

- Cross-check a laboratory report identifying errors and omissions?
- Provide next steps to resolve or prevent the errors or omissions?

SELF-ASSESSMENT

For this activity, you will need:

- ❑ Handout: Errors Noted (801)
- ❑ Worksheet 1: Laboratory Report (802)
- ❑ Worksheet 2: Report for Review (803)
- ❑ Job Aid: Cross-checking Guidelines (804)

Errors Noted[801]

Cape Regional Laboratory

Report Date/Time: 5-10-2008 1500

Lab #: 32
Drawn by: SL
Collected Date/Time: 3-10-2008 0815

Hematology

[X] CBC — Tech initials: SL

Results		Adult Normal Values		
15.3	WBC	M 3.3 - 10.0	F 3.4 – 9.8	x10³/ul
3.94	RBC	4.35 - 5.9	3.69 – 5.13	x10⁶/ul
11.0	HGB	13.7 - 16.7	11.7 – 14.5	g/dl
32.0	HCT	40.5 - 49.7	34.1 – 44.3	%
68.9	MCV	79.7 – 92.0	81.5 – 96.7	fl
22.6	MCH	26.1 – 33.3	26.5 – 33.5	pg
31.0	MCHC	32.2 – 35.0	31.9 – 35.3	g/dl
1.60	RDW	11.6 – 14.4		%
122	PLT	140 - 440		x10³/ul

[X] Differential — Tech initials: C

		Adult Normal Values
85	Neutrophils	45 – 66%
10	Bands (Neutrophilic)	1 – 12%
7	Lymphocytes	20 – 40%
	Atypical Lymphocytes	0 – 2%
	Monocytes	4 – 10%
	Eosinophils	1 – 6%
	Basophils	0 – 2%
	Other	

RBC Morphology [ ] Normal Morphology

		Morphology Terms
	Anisocytosis	1 = Slight 2 = Moderate 3 = Marked
	Microcytosis	
+2	Macrocytosis	
+1	Hypochromia	
	Poikliocytosis	

Chemistry

[ ] Basic [ ]Comprehensive [ ] LFT [ ] Lipid — Tech initials: C

	Result	Normal (M / F)		Result	Normal (M / F)
[ ] GLUC		3.9 – 5.8 mmol/l -fasting	[X] ALT	30.1	< 41 / < 31 U/L
[X] UREA	4.9	2.5 – 6.4 mmol/L	[ ] AST		< 37 / < 31 U/L
[ ] Na		136 - 145 mmol/L	[ ] ALP		53 – 128 / 42 – 98 U/L
[ ] K		3.5 – 5.3 mmol/L	[ ] CK		38 – 171 / 26 – 145 U/L
[ ] Cl		98 - 110 mmol/L	[ ] LDH		230 – 460 U/L
[X] CREAT	418	62–115 / 53 -97 umol/L	[ ] AMY		27 – 102 U/L
[ ] URIC ACID		208– 430 155 - 360 umol/l	[X] CALCIUM		2.15 – 2.50 mmol/L
[ ] T- PROT		64 – 83 g/L	[X] PHOS		0.87–1.45 mmol/L
[ ] ALBUMIN	60	35 – 52 g/L	[ ] CHOL		3.6 – 5.7 mmol/L
[X] T-BILI	5	5.1 – 20.5 umol/L	[ ] TRIG		< 2.26 mmol/L
[X] D-BILI		0.0 – 3.4 umol/l	[ ] HDL-C		0.78 – 1.94 / 0.85–2.38 mmol/L
[ ] GGT		< 55 / < 38 U/L	[ ] calc LDL-C		< 1.71 – 5.44 / 1.48–5.80 mmol/L
[ ] Glucose Result by Glucometer		4.1 – 5.9 mmol/l -fasting			

Additional In-House Testing

Tech initials: AM			Normal Values
[X] Urine Pregnancy	POS	NEG	N/A
[ ] CRP	POS	NEG	NEG
[ ] Malaria Rapid	POS	NEG	NEG
[ ] RPR	WEAK REACTIVE / REACTIVE	NON REACTIVE	NON REACTIVE
[ ] KOH	Source:		
[ ] Saline Prep			
[ ] Gram Stain			

CCMS Urinalysis

[X] Tech initials: AM

		Normal Values
yellow	Color	N/A
hazy	Appearance	N/A
16	Urobilinogen	<16 umol/L
neg	Glucose	Negative (mmol/L)
neg	Bilirubin	Negative (ummol/L)
neg	Ketones	Negative (mmol/L)
1.052	Specific Gravity	1.005 – 1.030
moderate	Blood	Negative
6.5	pH	5.0 – 8.0
1.0	Protein	Negative (g/L)
+	Nitrite	Negative
moderate	Leukocytes	Negative

[X] Microscopic — Tech initials: C

	WBC/HPF	Crystals:
10-20	RBC/HPF	
	EPI-renal/HPF	Casts/LPF:
5-10	EPI-squamous /HPF	
	Bacteria	Trichomonas / Yeast / Parasite:
	Mucus	

Quality Assurance

Date Requested: 3/10/08 — Ordering Doctor: Smith

[X] Routine [ ] Stat [ ] Waiting [X] Fasting [ ] Non-Fasting

QA Review:

Date: ___/___/___ Comments: _____

Doctor Signature: _____

Patient Information

Name (surname, first): _____

D.O.B.: ___/___/___ Age: _____ [ ] Male [ ] Female

Patient No.: _____

Diagnosis:

Laboratory Report[802]

Cape Regional Laboratory

Report Date/Time: 5-10-2008 1500

Lab #: 32
Drawn by: SL
Collected Date/Time: 3-10-2008 0815

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	Mucus	

Quality Assurance

Date Requested: 3/10/08
Ordering Doctor: Smith

[X] Routine [ ] Stat [ ] Waiting [X] Fasting [ ] Non-Fasting

QA Review:

Date: ___/___/___ Comments: _____

Doctor Signature: _____

Patient Information

Name (surname, first): _____

D.O.B.: ___/___/___ Age: _____ [ ] Male [ ] Female

Patient No.: _____

Diagnosis:

Report for Review[803]

Cape Regional Laboratory

platelet count verified by peripheral smear critical plt called to Dr Smith at 1122 3-10-08 SL

Report Date/Time: 3-10-2008 1500

Lab #: 32
Drawn by: SL
Collected Date/Time: 3-10-2008 0815

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Additional In-House Testing

Tech initials: AM

				Normal Values
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[ ] Gram Stain

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moderate	Bacteria	Trichomonas / Yeast / Parasite:
	Mucus	

Quality Assurance

Date Requested: 3/10/08
Ordering Doctor: Smith

[☒ Routine [ ] Stat [ ] Waiting [☒ Fasting [ ] Non-Fasting

QA Review:

Date: ____/____/____ Comments: _____

Doctor Signature: _____

Patient Information

Name (surname, first): _____

D.O.B.: ____/____/____ Age: _____ [ ] Male [ ] Female

Patient No.: _____

Diagnosis:

Cross-Checking Guidelines[804]

Items to be verified prior to release of test results

Completeness

- Each test has a corresponding result
- Patient information
- Clinical information
- Provider information
- Specimen information
- Collection information
- Initials of staff member who performed each test indicated
- Date and time of report
- Result information identical with log book

Critical (Panic Values)

- Result verified and verification documented
- Documentation of result notification
  - On result report
  - In log book

Testing Priority

- STAT request's communicated and documented
- Delays communicated and documented

Specimen Rejection

- Reason for specimen rejection documented
- Clinician and / or patient notified and this notification is documented

Result Information

- Legible
- Proper placement of decimals
- Uniform result alignment with regards to decimal placement
- Format of results corresponds with SOP
- Proper units and significant places
- Abbreviations used from approved list
- Within instrument linearity
- No associated instrument codes with regard to accuracy
- Result corresponds with correct test
- Diluted results multiplied with correct dilution factor
- No consistent pattern or trend exhibited between patients for a specific analyte during cross-checking unless patient grouping under review is from the same diagnosis/population pool (i.e. Newborn hemoglobin and hematocrit)

Appropriateness

- Test relevant to patient's age and gender
- Result information makes clinical sense
  - Electrolytes
  - BUN/Creatinine
  - Macroscopic with microscopic
  - Instrument with smear
  - RBC Indices, RBC count, Hemoglobin and Hematocrit all show agreement