MODULE 8 Laboratory Testing

My lab provides prompt, accurate and validated test results.

SLMTA Participant's Manual

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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.

-	the fol	lowing 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	<u>Laboratory Quality Manual</u> Is there a current laboratory quality manual, composed of the quality management system's policies and has the manual
Laboratory Strengthening Checklist Automatical and the second strengthening and the second strengthenin	1.5	content been communicated to, understood and implemented by all staff? <u>Laboratory Policies and Standard Operating Procedures</u> 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	<u>Product Expiration</u> 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
	8.2	available to persons responsible for primary sample collection? Does the laboratory adequately collect information needed for examination performance?
	8.3	Are adequate sample receiving procedures in place?
	8.4	<u>Pre-examination Handling</u> , <u>Preparation and Storage</u> 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	<u>Reagents Acceptance Testing</u> 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?
		Are environmental conditions checked and reviewed accurately?
	9.1	<u>Test Result Reporting System</u> Are test results legible, technically verified by
	9.2	an authorized person, and confirmed against patient identity? <u>Testing Personnel</u> Are testing personnel identified on the result report or attended against a standard against again
	9.3	other records (manual or electronic)? Report Content
	9.3 9.8	Test Result Are test results validated, interpreted and released by
	10.3	appropriately-authorized personnel? 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 fo	lowing 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
Chaoklint Itoma	4 5	Laboratory Delinics and Standard Operating Dreadyres Are relinics and/or
<section-header><section-header><section-header><section-header><section-header><section-header><text><text><text></text></text></text></section-header></section-header></section-header></section-header></section-header></section-header>	 1.5 9.1 9.2 9.3 9.4 	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) <u>Test Result Reporting System</u> Are test results legible, technically verified by an authorized person, and confirmed against patient identity? <u>Testing Personnel</u> Are testing personnel identified on the result report or other records (manual or electronic)? <u>Report Content</u> <u>Analytic System/Method Tracing</u> When more than one instrument is in use for the same test are test assults to the assument used for testing?
	9.8	the same test, are test results traceable to the equipment used for testing? <u>Test Result</u> 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 Noted⁸⁰¹

Cape Regio Laboratory		Report	Date/Time:	5-10-2	008)	Lab #: 3 Drawn b	Y: SL			
				1500 Collected Date/Time: 3-10-2008 08						
		Hematology	and the last of th	Additional In-House Testing						
CBC			Tech initial	s: SL		Tech initials: AM				
Results			ormal Values	1	KI Urine Pregnanc			NEG	N/A	
15.3	15,3 WBC * 3.3 - 10.0		^r 3.4 – 9.8 x10 ³ /ul		[]CRP PC			NEG	NEG	
940	RBC	4.35 - 5.9	3.69 - 5.13	x10 ⁶ /ul	[] Malaria Rapid	POS VEAK		NEG NON	NEG	
11.0	HGB 13.7 - 16.7		11.7 - 14.5	g/dl		ACTIVE	REACTIVE	REACTIVE	REACTIVE	
32.0	HCT	40.5 - 49.7	34.1 - 44.3	%	[]KOH		Sou	urce:		
68.9	MCV	79.7 - 92.0	81.5 - 96.7	fl	[] Saline Prep					
22.6	MCH	26.1-33.3	26.5 - 33.5	pg	[] Gram Stain					
31.0	MCHC	32.2 - 35.0	31.9 - 35.3	g/dl						
.60	RDW	11.6	6-14.4	%						
(22)	PLT	140) - 440	x10 ³ /ul		CC	MS Urinaly	vsis		
Differential	Tech i	nitials: 🔿	Adult No	rmal Values	Tech	initials:	AM	Norr	nal Values	
85	Neutrophils		45 -	- 66%	vellow		Color		N/A	
10	Bands (Neut	rophilic)	1	12%	hazy		Appearance		N/A	
7/	Lymphocyte	S	20 -	- 40%	16		Urobilinogen	<1	6 umol/L	
C	Atypical Ly	nphocytes	0 -	- 2%	may		Glucose	Negativ	ve (mmol/L)	
Monocytes			4 -	10%	meg		Bilirubin	Negativ	/e (ummol/L)	
	Eosinophils		1 -	- 6%	mean]	Ketones	Negati	gative (mmol/L)	
	Basophils		0 -	- 2%	(1.05			1.00	1.005 - 1.030	
	Other				mode	rate	Blood		Negative	
RBC Morpholog	gy	[] Normal	Morphology		(65) pH			5.0-8.0		
	Anis	ocytosis	Mambala	m Tauma	Le Protein			Negative (g/L)		
		Microcytosis	Morphology Terms		()		Nitrite	trite 1		
(+2)		Macrocytosis	1 = Slight 2 = Moderate		moderate		Leukocytes	Negative		
+1	Нурс	ochromia	3 = Mark		[x] Microscop	Microscopic Tech initials:			\sim	
	Poik	iocytosis			\bigcirc	WBC/HPF	Crystals:			
		Chemistry			10-20	RBC/HPF				
] Basic []Con	prehensive	[]LFT []	Lipid T	ech initials		EPI-renal/H	PF Casts/LPF:			
R	onult	ormal A / F)	Result	Normal (M / F)	5-10	EPI- squamous /HPF	8			
] GLUC		3.9 – 5.8 1/1 -fasting 2.5 – 6.4	LT (30.1	 < 41 / < 31 U/L < 37 / < 31 	\bigcirc	Bacteria	Trichomona	Trichomonas / Yeast / Parasite:		
JUREA (4,	9)	mmol/L	ST	U/L	L	Mucus				
] Na		136 - 145 mmol/L [] A	LP	53 - 128 / 42 - 98 U/L		Qu	ality Assura	nce		
] K		3.5 – 5.3 mmol/L []C	К	38 - 171 / 26 - 145 U/L	Requested: 3/10/08 Docion Smith					
]CI	62-1	98 - 110 []L mmol/L []L		230 - 460 U/L 27 - 102	OA Review:	[] Stat [] Waiting [Fasting [] N	on-Fasting	
URIC ACID	18 02-1	umol/L []A	ALCIUM	U/L 2.15-2.50	Date:/	Comn	nents:			
] T- PROT		360 umol/I / 1 / C 4 − 83 g/L [√ P]		0.87–1.45 mmol/L	Doctor Signature:					
	2.0 3	5 – 52 g/L []C	HOL	3.6 - 5.7 mmol/L	.7 Patient Information					
T-BILI	*5)	5.1-20.5 umol/L []T		< 2.26 mmol/L 0.78 - 1.94 /	Name (surname, fi	rst):				
D-BILI		- 3.4 umol/I [] H	ılc	0.85–2.38 mmol/L < 1.71 – 5.44 /		/	Age:	[]M	ale []Femal	
] GGT] Glucose Result	< 33	/ < 38 U/L LDL-		.48-5.80 mmol/L	Patient No.: Diagnosis:					
		41-341			I DRIVINGSIN.					

Laboratory Report⁸⁰²

Cape Regio		D	mort De	to/Time	5-10-2	008	D	ab #: 3d rawn by:				
Laborator	y	K	eport Da	te/11me:	5-10-a	150				me: 3-10-	2008 08	
The second second		Hemate	ology				Au	lditional	In-Hoi	use Testing		
CBC			ech initia	Is: SL	Tech initials: AM					Normal Values		
Results			dult Normal Values			Virine Pregnancy P		POS		NEG	N/A	
15.3	15,3 WBC [№] 3.3 - 10.0		10.0	0.0 ¹⁷ 3.4 – 9.8 x10 ³ /ul		[] CRP		POS		NEG	NEG	
94	RBC 4.35 - 5.9		- 5.9	3.69 - 5.13	x10 ⁶ /ul	[] Malaria Rap				NEG	NEG	
11.0			16.7	11.7 - 14.5	g/dl	[]RPR	WEA REACT		EACTIVE	NON REACTIVE	NON REACTIVE	
22.0	HC	CT 40.5 -	49.7	34.1 - 44.3	%	[]KOH Sou		Source:	rce:			
689	MC	CV 79.7 -	- 92.0	81.5 - 96.7	fl	[] Saline Prep	aline Prep					
22.6	MC	сн 26.1 -	- 33.3	26.5 - 33.5	pg	[] Gram Stain	am Stain					
31.0	MCI	НС 32.2 -	- 35.0	31.9 - 35.3	g/dl							
.60	RD	w	11.6 - 14	.4								
122	PL	T	140 - 44	0	x10 ³ /ul			ССМ	S Urin	alysis		
Differential	Т	ech initials:		Adult No	ormal Values	🕅 Te	ch ini	tials:)	AM	No	ormal Values	
85	Neutro	ophils		45	- 66%	vello	W	Col	or		N/A	
10	Bands	(Neutrophilic)		1 -	- 12%	hazy		App	earance		N/A	
7	Lymp	hocytes		20	- 40%	16		Uro	bilinogen	<	16 umol/L	
	Atypic	cal Lymphocytes		0	- 2%	norg		Glu	Glucose		Negative (mmol/L)	
Monocytes Eosinophils			4	- 10%	neg		Bili	Bilirubin		Negative (ummol/L)		
			1	- 6%			Ket	ones	Nega	Negative (mmol/L)		
	Basophils				0-2%			Spe	Specific Gravity		1.005 - 1.030	
Other					1.052 Spe moderate Blo		od	l Negative				
RBC Morphology [] Norm				rmal Morphology			65 pH			5.0 - 8.0		
	Anisocytosis		Mornhology Terms			I.O Prote		tein	Negative (g/L)			
Microcytosis		sis	Morphology Terms				Nitr	ite		Negative		
+2		Macrocyto	sis	s 1 = Slight 2 = Moderate		moderate		e Leu	kocytes	Negative		
+1		Hypochromia		3 = Mar		[×] Microscopic			Tech i	Tech initials:		
		Poikliocytosis					1	WBC/HPF	Crystals			
		Chem	istry			10-2	0	RBC/HPF				
] Basic []Co	mprehens	sive []LFT	[]Lipi	id '	Fech initials			Pl-renal/HPF	Casts/LP	F:		
1	Result	Normal (M / F)		Result (M / F)		FIC		EPI- squamous				
] GLUC		3.9 - 5.8	ALT	28	< 41 / < 31	5-10 APF Bacteria		Trichom	Trichomonas / Yeast / Parasite:			
		mmol/l -fasting 2.5-6.4		30.	U/L < 37 / < 31			Bacterra		ionas / i cast / rai	lashe.	
JUREA 4	.9	mmol/L	[] AST		U/L			Mucus				
] Na		136 - 145 mmol/L	[]ALP		53 - 128 / 42 - 98 U/L	fugity Accurated						
]К		3.5 - 5.3 mmol/L	[]СК		Date Ordering Doctor: Smith							
] CI		98 - 110 mmol/L	[]LDH		230 – 460 U/L	Rout	ine []Stat []V	Vaiting	[Fasting []]	Non-Fasting	
CREAT 4	18	62–115 / 53 -97 umol/L	[] AMY		27 – 102 U/L	QA Review:						
] URIC ACID		208-430 155 - 360 umol/I	[x] CALC	IUM	2.15 - 2.50 mmol/L	Date:/	/	_ Comment	s:			
		64 – 83 g/L	[√ PHOS		0.87-1.45 mmol/L	Doctor Signatu	ire:					
] T- PROT	0.0	35 – 52 g/L	[]CHOL		3.6 - 5.7 mmol/L			Patien	t Infor	mation		
	Die	5.1 - 20.5	[] TRIG		< 2.26 mmol/L	Name (surname	e, first):					
] ALBUMIN (.5	umol/L	[] Indo									
] ALBUMIN (∫T-BILI	.5			2	0.78 - 1.94 / 0.85-2.38 mmol/L	D.O.B.:	/	A	\ge:	[]]	Male [] Female	
] T- PROT] ALBUMIN (•5	umol/L				D.O.B.: Patient No.:	/	A	\ge:		Male []Female	

Report for Review⁸⁰³

Cape Regio Laboratory		smear	CI	ritical p	ified by 1 at 112	-0 Dr Si 2 3-10	-08 I	Drawn	3⊋ by:≦	SL				
Laboratory		IX.			3 1500		SL (Collec	ted Da	ate/Time:	3-10-20	08 0810		
		Hemato	logy				A	dditie	onal I	n-House	Testing			
CBC			Т	ech initial	Tech initials: AM						Normal Values			
Results	sults		dult Normal	Values		[] Urine	Pregnancy	PO	OS		NEG	N/A		
15.3	WB	sc м 3.3 -	10.0 ^{F/}	3.4 - 9.8	x10 ³ /ul	[]CRP		PO	OS	_	NEG	NEG		
3,96	RB	C 4.35	- 5.9	3.69 - 5.13	x10 ⁶ /ul	[] Malar		PO	OS		NEG	NEG		
11.0	HG		16.7 11.7 – 14.5 g/dl [] RPR REACTIVE REACTIVE REA						NON REACTIVE	NON REACTIV				
33.0	HC	T 40.5 -	49.7	34.1 - 44.3	%	[]KOH Source				rce:				
68.9	MC	V 79.7 -		81.5 - 96.7	fl	[] Saline Prep								
22.6	MC	сн 26.1 –	33.3	26.5 - 33.5	pg	[] Gram	Stain							
31.0	MCI	HC 32.2 -	35.0	31.9 - 35.3	g/dl									
16.0	RD		11.6 - 14	.4	%									
22	PL	T (22)	140 - 44	0	x10 ³ /ul				CCMS	Urinalys	sis			
Differential	Т	ech initials: (5W	Adult No	rmal Values	W	Tech in	itials:	AY	η	Nor	mal Values		
85	Neutro	ophils		45 -	- 66%	ve	llow		Color			N/A		
10	Bands	(Neutrophilic)		1 -	- 12%		ZY		Appea	irance		N/A		
5	Lymp	hocytes		20 -	- 40%	16	/		Urobi	linogen	<1	6 umol/L		
	Atypical Lymphocytes				- 2%	ne	gati	ve	Gluco	se	Negati	ve (mmol/L)		
	cytes		4 -	- 10%	negative Bilirubin				bin	Negative (ummol/L)				
	Eosine	ophils		1 -	- 6%	ne			Keton	tones Neg		Negative (mmol/L)		
	Basop	hils		0-2%			025		Specif	ic Gravity	vity 1.005 – 1.030			
	Other						moderate Blood				Negative			
RBC Morpholo	gy	[] N	lormal Morphology			6.5 pH				5.0 - 8.0				
+1		Anisocytosis	Mornhology Tarms			1.0 Protein					Neg	Negative (g/L)		
+2		Microcytos	is Morphology Terms		positive Nitrite				٢	legative				
		Macrocyto	sis $1 = $ Slight $2 = $ Moderate			moderate Leukocytes				Negative				
+1		Hypochromia		3 = Marked		[x] Microscopic			Tech initial		ils: AM			
		Poikliocytosis				5-	10	WBC/H	PF	Crystals:				
		Chem	istrv				20	RBC/H	PF					
Basic Con	nprehens	ive []LFT	[] Lipi	d T	Fech initials	10		EPI-rena	l/HPF	Casts/LPF:				
F	lesult	Normal (M / F)	Result Normal &V (M / F)		3	-5	EPI- squamo	ous						
[]GLUC		3.9 - 5.8 mmol/l -fasting	[ALT	30	< 41 / < 31 U/L	moderate Bacteria Trichomonas / Yeast / Paras				site:				
WUREA L	1.9	2.5 - 6.4 mmol/L	[] AST		< 37 / < 31 U/L	Mucus								
] Na		136 - 145 mmol/L	[] ALP		53 - 128 / 42 - 98 U/L			Q		Assuran	ice			
[]K		3.5 – 5.3 mmol/L	[]CK		38 - 171 / 26 - 145 U/L	Date Requested	1:3/10	108	Orde	or :	nith			
[]Cl		98 - 110 mmol/L	[]LDH 230-460 U/L				[] Stat	[] Wa	iting [∦ Fa	asting []N	on-Fasting			
		[] AMY	U/L											
] URIC ACID		208-430 155 - 360 umol/L		им 2.3	0.87 1.45			Co	mments:					
[] T- PROT		64 - 83 g/L 35 - 52 g/L	[X PHOS	1.0	5 mmol/L 3.6-5.7	Doctor S	ignature: _							
[]ALBUMIN	6	5.1-20.5	[]CHOL		mmol/L < 2.26			Pa	tient	Informat	ion			
AT-BILI 6	•0	umol/L 0.0 – 3.4 umol/L	[] TRIG		mmol/L 0.78-1.94 /		rname, first							
I GGT	.5	< 55 / < 38 U/L	[] calc	0	0.85–2.38 mmol/L < 1.71 – 5.44 /	D.O.B.:		/	Ag	2:	[]M	ale []Fema		
] Glucose Result		4.1 - 5.9	LDL-C	1	.48-5.80 mmol/L	Patient No Diagnosis								

Cross-Checking Guidelines⁸⁰⁴

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
 - \circ 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
 - o Electrolytes
 - o BUN/Creatinine
 - Macroscopic with microscopic
 - o Instrument with smear
 - RBC Indices, RBC count, Hemoglobin and Hematocrit all show agreement