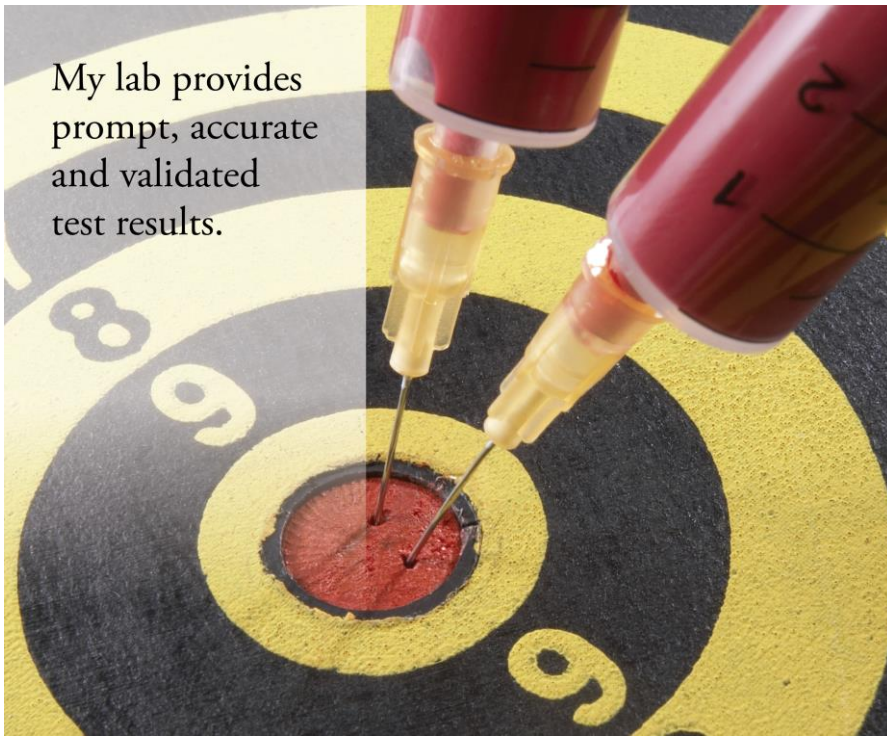
# MODULE 8

## Laboratory Testing




SLMTA Participant's Manual

# TABLE OF CONTENTS

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

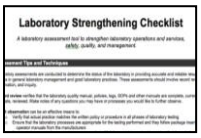
# ACTIVITY SUMMARY SHEET

## 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 accreditation preparedness checklist items**

| | |
|---|---|
| Management Tasks  | 6.4 Validate new equipment, reagents, and supplies<br>7.3 Enforce good specimen handling and processing practices<br>8.4 Validate assigned tests and specific abnormal results |
| Checklist Items   | 1.1 Laboratory Quality Manual Is there a current laboratory quality manual, composed of the quality management system's policies and procedures, and has the manual content been communicated to and understood and implemented by all staff?<br>1.4 Laboratory Policies and Standard Operating Procedures Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel? (Purchasing and Inventory Control, Specimen Storage and Retention, Examination SOPs, Interrupted Services, Examination Validation/Verification, Quality Assurance)<br>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?<br>7.14 Product Expiration Are all reagents/test kits in use (and in stock) currently within the manufacturer-assigned expiration dates or within stability?<br>8.1 Are guidelines for patient identification, specimen collection (including client safety), labeling, and transport readily available to persons responsible for primary sample collection?<br>8.2 Are adequate sample receiving procedures in place?<br>8.3 Are specimens stored appropriately prior to testing?<br>8.6 Is complete procedure manual available at the workstation or in the work area?<br>8.7 Is there a reagent logbook for lot number and dates of opening that reflects verification of new lots?<br>8.8 Is each new lot number, new shipment of reagents, or consumables verified before use?<br>8.9 Is internal quality control performed, documented, and verified before releasing patient results?<br>8.11 Are environmental conditions are checked and reviewed accurately?<br>9.1 Test Result Reporting System Are test results legible, technically verified by an authorized person, and confirmed against patient identity?<br>9.2 Testing Personnel Are testing personnel identified on the requisition and record?<br>9.3 Test Result Records Are test results recorded in a logbook or electronic record in a timely manner?<br>9.8 Test Result Report Is the laboratory result report(s) in a standard form determined to be acceptable by its customers?<br>9.9 Test Result Are test results validated, interpreted and released by appropriately-authorized personnel?<br>10.3 Is corrective action performed on all non-conforming aspects of the quality management system documented? |

## 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?

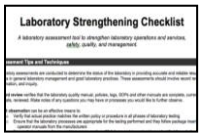
## SELF-ASSESSMENT

# 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 accreditation preparedness checklist items | |
|---|---|
| Management Tasks  | 8.1 Monitor testing to ensure SOPs are followed and tests are performed and reported properly and promptly<br>8.2 Cross-check test reports against test request to ensure completion of all tests<br>8.3 Review test records and findings promptly to ensure accuracy and timely release of test results<br>8.4 Validate assigned tests and specific abnormal results<br>9.1 Aggregate and report all test findings for each patient |
| Checklist Items   | 1.4 Laboratory Policies and Standard Operating Procedures Are policies and standard operating procedures (SOPs) for laboratory functions current, available and approved by authorized personnel? (Identification and Control of Nonconformities, Quality and Technical Records, Authorization, Reporting of Results)<br>8.14 Are test requests checked with test results, thereby assuring the accuracy and completion of all tests?<br>9.1 Test Result Reporting System Are test results legible, technically verified by an authorized person, and confirmed against patient identity?<br>9.2 Testing Personnel Are testing personnel identified on the requisition and record?<br>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?<br>9.5 Result Cross-check System Is there a system for reviewing for transcription errors?<br>9.8 Test Result Report Is the laboratory result report(s) in a standard form determined to be acceptable by its customers?<br>9.9 Test Result Are test results validated, interpreted and released by appropriately-authorized personnel?<br>10.3 Is corrective action performed on all non-conforming aspects of the quality management system documented? |

## 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<br>2 = Moderate<br>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

| | | |
|---|---|---|
| C | WBC/HPF | Crystals: |
| 10-20 | RBC/HPF | |
| | EPI-renal/HPF | Casts/LPF: |
| 5-10 | EPI-squamous /HPF | |
| C | 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

## 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:

| | | 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

| | |
|---|---|
| | Anisocytosis |
| | Microcytosis |
| +2 | Macrocytosis |
| +1 | Hypochromia |
| | Poikliocytosis |

**Morphology Terms**
1 = Slight
2 = Moderate
3 = Marked

## Chemistry

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

| | 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 | 6.0 | 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:

| | | |
|---|---|---|
| | 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:

# 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

## Hematology

☒ CBC — Tech initials: SL

| Results | | Adult Normal Values | | |
|---|---|---|---|---|
| 15.3 | WBC | M 3.3 - 10.0 | F 3.4 – 9.8 | x10³/ul |
| 3.96 | RBC | 4.35 - 5.9 | 3.69 – 5.13 | x10⁶/ul |
| 11.0 | HGB | 13.7 - 16.7 | 11.7 – 14.5 | g/dl |
| 33.0 | 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 |
| 16.0 | RDW | 11.6 – 14.4 | | % |
| 22 | PLT (22) | 140 - 440 | | x10³/ul |

☒ Differential — Tech initials: GW

| | | Adult Normal Values |
|---|---|---|
| 85 | Neutrophils | 45 – 66% |
| 10 | Bands (Neutrophilic) | 1 – 12% |
| 5 | Lymphocytes | 20 – 40% |
| | Atypical Lymphocytes | 0 – 2% |
| | Monocytes | 4 – 10% |
| | Eosinophils | 1 – 6% |
| | Basophils | 0 – 2% |
| | Other | |

**RBC Morphology** [ ] Normal Morphology

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

## Chemistry

[ ] Basic [ ] Comprehensive [ ] LFT [ ] Lipid — Tech initials GW

| | Result | Normal (M / F) | | Result | Normal (M / F) |
|---|---|---|---|---|---|
| [ ] GLUC | | 3.9 – 5.8 mmol/l -fasting | ☒ ALT | 30 | < 41 / < 31 U/L |
| ☒ UREA | 14.9 | 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 |
| ☒ CREAT | 418 | 62–115 / 53 -97 umol/L | [ ] AMY | | 27 – 102 U/L |
| [ ] URIC ACID | | 208– 430 / 155 - 360 umol/l | ☒ CALCIUM | 2.30 | 2.15 – 2.50 mmol/L |
| [ ] T- PROT | | 64 – 83 g/L | ☒ PHOS | 1.05 | 0.87–1.45 mmol/L |
| [ ] ALBUMIN | | 35 – 52 g/L | [ ] CHOL | | 3.6 – 5.7 mmol/L |
| ☒ T-BILI | 6.0 | 5.1 – 20.5 umol/L | [ ] TRIG | | < 2.26 mmol/L |
| ☒ D-BILI | 0.5 | 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 |
|---|---|---|---|---|
| ☒ 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

☒ Tech initials: AM

| | | Normal Values |
|---|---|---|
| yellow | Color | N/A |
| hazy | Appearance | N/A |
| 16 | Urobilinogen | <16 umol/L |
| negative | Glucose | Negative (mmol/L) |
| negative | Bilirubin | Negative (ummol/L) |
| negative | Ketones | Negative (mmol/L) |
| 1.025 | Specific Gravity | 1.005 – 1.030 |
| moderate | Blood | Negative |
| 6.5 | pH | 5.0 – 8.0 |
| 1.0 | Protein | Negative (g/L) |
| positive | Nitrite | Negative |
| moderate | Leukocytes | Negative |

☒ Microscopic — Tech initials: AM

| | | |
|---|---|---|
| 5-10 | WBC/HPF | Crystals: |
| 10-20 | RBC/HPF | |
| | EPI-renal/HPF | Casts/LPF: |
| 3-5 | EPI-squamous /HPF | |
| 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