Date(s) of Assessment\_

1. GENERAL INFORMATION

Laboratory Name\_

Physical

Address

Mailing Address

Telephone# \_Fax#\_

Email:\_

Laboratory Owner

Laboratory Director

1.1 Is there an organizational chart for the lab?

1.2 Is there a list of personnel employed by this lab?

1.3 Have there been any recent changes in personnel?

1.4 What is the average length of time of employment for the technical staff?

1.5 Is there a list of tests performed by the lab?

1.6 Is all testing performed on site?

1.7 How long has the laboratory been at this location?

1.8 Are there multiply locations/testing sites for the lab?

1.9 Have there been any recent changes in the facilities or the equipment? (major repairs, new equipment, etc)?

1.10When was the lab lasted audited? By what group/agency?

2. GENERAL WALK THROUGH

Walk through the facility following the normal workflow as much as possible. Observe use of space, condition of the facility, personnel, equipment, safety precautions and any work currently in process. Make note of any areas that stand out for specific attention later. Identify who you will be working with the various areas of the laboratory assessment.

3. GENERAL POLICIES

3.1 Written procedures

Is there a standard format for written procedures?

Is there an approval system for written procedures?

How are revised procedures handled?

3.2 Is there a written general quality control plan for the laboratory?

3.2 Does the quality control plan include control material to be used and frequency of use?

3.3 Is there a written general quality assurance plan for the laboratory?

3.3 Does the quality assurance plan include documentation of problems and corrective action taken?

3.4 Does the laboratory participate in proficiency programs for each of the analytes tested?

Which programs?

Frequency?

How are the proficiency samples handled?

Who tests the proficiency samples?

Who reviews the proficiency results?

What action is taken if results are not within guidelines given?

3.5 Is there a general preventative maintenance policy for the laboratory?

3.6 How is the preventative maintenance, monitoring or calibration handled for the following?

Pipettes

Thermometers

Timers

Centrifuges

Water\_

Clean/Dirty Glasswear

Plate Washer

Plate Reader

Thermocycler

Incubators

Hoods

Bench Tops/Counters

3.7 For temperature sensitive equipment such as incubators, refrigerators and freezers:

Are the temperatures monitored and recorded daily?

Are the acceptable temperature ranges listed on the monitoring records?

What action is taken if the temperatures are out of range?

Is the room temperature monitored and recorded?

How are temperatures monitored when staff is not present?

Are liquid nitrogen freezers in use? Is the liquid nitrogen level monitored?

4. PERSONNEL ASSESSMENT

4.1 How are new personnel trained? Records?

4.2 How are existing personnel trained on new equipment or procedures?

4.3 How is the technical competency of the laboratory staff monitored?

4.4 Are Department meetings held? Frequency? Who chairs? Records?

5.0 SAMPLE MANAGEMENT

5.1 Collection of laboratory specimens:

Where are the specimens collected?

Who collects the specimens?

How are the specimens transported to the lab?

Are there guidelines for collection, labeling, preservation and handling?

Is there a unique identification for each patient specimen?

What procedures are in place to prevent mislabeling or mishandling?

5.2 Receipt of laboratory specimens:

How are the laboratory specimens received?

Are there guidelines for acceptation and rejection of specimens?

How is a rejected specimen handled?

What are the acceptance criteria for specimens?

5.3 Processing of laboratory specimens:

How are the specimens processed?

How are the specimens checked for correct labeling ?

How are the specimens stored pending testing?

Are specimens stored in a manner that assures specimen integrity prior to testing?

5.4 Testing of specimens:

How is the testing ordered?

Is there a pending worklist for the technologist to follow?

What checks are used to make sure a test request is not missed?

What checks are used to assure an ordered test was performed?

5.5 Is there a policy for retaining tested specimens?

5.5 Freezer Storage

How are specimens handled for long term storage?

What system is used to store and retrieve frozen specimens?

Are repeated freeze/thaws recorded by sample?

What is the acceptable temperature range for long term freezer storage of samples?

6.0 TEST SYSTEMS

6.1-6.10 The following questions apply in general to all tests.

6.1 Are there written procedures for each test performed?

6.2 Are all test modifications or changes approved by the laboratory director and included in the written procedure?

6.3 Are procedures current and reviewed by the laboratory director? Date of last review?

6.4 If package inserts are used for procedures, are they supplemented with specific instructions where needed?

6.5 What mechanism is used to determine if the procedures are being followed?

6.6 What action is taken if patient test values are outside the test systems linear/reportable range?

6.7 Critical Values:

Is there a critical value policy?

Are critical values posted?

What action is taken for critical values?

6.8 If dilutions are made on a sample, are the dilutions and calculations recorded on the worksheets?

6.9 How are exceptions to the written procedures handled?

6.10What steps are taken to add a new test method or instrument to the lab?

6.11-6.21 The following questions are test specific

6.11Do the test records identify who performed the test?

6.12Are the original test records stored? For how long?

6.13Are the QC requirements listed in the procedures?

6.14Are a minimum of two levels of controls run each day of testing?

6.15How are QC values determined?

6.16Are QC results documented and reviewed?

6.17Are calibration requirements documented and followed?

6.18What is the frequency of calibration?

6.19Are maintenance requirements documented and followed?

6.20Are problems and corrective action documented for each test or instrument?

6.21Are the calibration, maintenance and corrective action records reviewed periodically and signed?

7.0 RESULTS

7.1 Who reviews the test results?

7.2 How are test results reviewed? Does the reviewer sign/initial the final results?

7.3 Are individual results reviewed for correlation with each other (ie hgb/hct)?

7.4 What parameters are reviewed for correlation of patient results?

7.5 What action is taken if individual results do not correlate with each other?

7.6 In what form(s) are results released from the laboratory?

7.7 Does the laboratory result report include reference ranges? age, gender specific?

7.8 How are critical values handled?

7.9 Does the report include a comments section?

7.10 What mechanism is used to detect reporting errors?

7.11 How are changes to reported results handled?

7.12 Is an exact copy of the original report kept by the lab? What form (hardcopy, computerized)? For how long?

8.0 RECORDS MANAGEMENT

8.1 Can a specimen be tracked from the test requisition through the test reporting?

8.2 How is the records storage system set up?

8.3Are the following records maintained and readily retrievable?

Requisitions/Test Orders

Worksheets, Instrument printouts

Test results or reports

QC records

8.4 How long are the above records maintained?

9.0 REAGENTS/SUPPLIES

9.1 How are reagents and supplies ordered?

9.2 Are there problems with acquiring supplies?

9.3 How are reagents/supplies received/stored?

9.4 How are expired reagents handled?

9.5 Are reagents properly labeled?

(name, concentration, storage requirements, date received/prepared, date in use, expiration date)

10 LABORATORY INFORMATION SYSTEMS (LIS)

10.1 Is there a mechanism to prevent alteration or destruction to major computer programs? (anti-virus programs)

10.2 Are there specific user levels within the LIS? (security levels)

10.3 Is there a policy on who is authorized to change information within the LIS?

10.4 Is there a system in place to prevent loss of results in case of hardware or software failure (backup/recovery)?

10.5 How often is backup performed?

10.6 What type of media is used for backup and where are the backup copies kept?

10.7 Is there scheduled maintenance on the hardware and software?

10.8 Is there a contingency plan for reporting results if the LIS fails?

10.9 Archiving:

Are results periodically archived?

Can the archived results be retrieved:

When are results archivied?

How long are the archived results maintained?

11 FACILITY

11.1 Are the environmental conditions (lighting, electricity, temperature, ventilation, space etc) appropriate for the work preformed?

11.2 In case of an electrical outage what steps are taken?

11.3 What type of back-up power supply is available?

11.4 How would samples be protected during an outage?

11.5 Is the electrical system adequately protected against electrical power interruptions and surges?

12 SHIPPING/TRANSPORTING

12.1 Is the laboratory involved in shipping of dangerous goods?

12.2 Is there a written policy for shipping dangerous goods?

12.3 Who handles the shipping of dangerous goods?

12.4 What training is required for employees involved in the shipping of dangerous goods?

12.5 Are certification records available?

13 SAFETY

13.1 Is there a biohazard safety policy?

13.2 Is personal protective gear available and used?

13.3 Is there a chemical hygiene plan?

13.4 Is there a hazardous chemical policy? MSDS available?

13.5 How is biohazard waste handled?

13.6 Are there periodic inspections of the electrical system?

13.7 Is the laboratory facility and workflow designed to enhance employee safety?

13.8 Is fire-fighting equipment (extinguishers) available? In-date?

14 COMMENTS

14.1 What are your main concerns for the laboratory at this time?

14.2 What would be of the most benefit for the lab at this time?