

SAMPLE SEA ICRN Laboratory Assessment Report Template

Name of the Laboratory:

Assessment conducted by:

Laboratory Supervisor/Head of Laboratory:

Date (s) of Visit:

Departments assessed:

Assessment tools and methods:

Report submission Date:

SUMMARY OF LABORATORY DEBRIEFING, SIGNIFICANT FINDINGS, AND RECOMMENDATIONS

For Pre-trial assessments, use the following format:

- I. LABORATORY ASSESSMENT
 - A. **Major Deficiencies** that must be corrected prior to trial initiation.
 - 1.
 - 2.
 - 3.
 - B. **Minor Deficiencies** that can be addressed on an ongoing basis.
 - 1.
 - 2.
 - 3.

For all other assessments, use this format:

- I. LABORATORY ASSESSMENT
 - Summarize findings

 - Recommendations or Corrective Actions**
Note these individually

STATUS OF PAST FINDINGS

DELETE THIS SECTION IF THIS IS THE FIRST LABORATORY ASSESSMENT

1. **Background information:**

Stat background of the study project

2. **Summary of the report: (Key findings and recommendations)**

3. **Observations and details Recommendations:**

3.1 Laboratory Management

Observation: _____

Recommendation: _____

3.2 Standard Operating Procedures (SOP)

Observation: _____

Recommendation: _____

2.4 Staff Training

Observation: _____

Recommendation: _____

2.5 Laboratory environment (Infrastructure, safety and arrangement)

Observation: _____

Recommendation: _____

2.6 Specimen Collection, Labeling and Handling

Observation: _____

Recommendation: _____

2.7 Equipment

Observation: _____

Recommendation: _____

2.8 Laboratory Reagents and Supplies

Observation: _____

Recommendation: _____

2.9 Laboratory Request Form, Laboratory Registration, Laboratory Reports

Observation: _____

Recommendation: _____

2.10 Quality Control Procedures and Programs

Observation: _____

Recommendation: _____

3. Any Other Observation/Recommendation/Training Requirement

Prepared by _____ **Title:** _____ **Date:** _____

Reviewed by _____ **Title:** _____ **Date:** _____