

## Quality Assessment Review Form and Checklist

These forms are used for periodical review of the patient testing process. These should be filed with the quality assessment records.

**Clinical Site:** \_\_\_\_\_

**Operator's Name:** \_\_\_\_\_

**Device Name:** Visby Medical – Sexual Health Test

Quality Assessment Activity	Comments	Date	Initials
<b>Patient Test Management:</b> Evaluate criteria for specimen submission, handling, and rejection; test results requisitions and reporting, accuracy and reliability of reports.			
<b>Quality Control:</b> Assess control data, errors in reporting results, and corrective actions taken with appropriate documentation records.			
<b>Proficiency Testing:</b> Review the effectiveness of corrective actions taken for unsatisfactory performance or failures.			
<b>Comparison of Test Results:</b> At least twice a year, review the comparative results for multiple methods, instruments, or site correlations when more than one procedure exists.			
<b>Relationship of Patient Test Information to Test Results:</b> Evaluate patient test reports for accuracy of patient information, test results, and normal ranges. Identify and evaluate results inconsistent with patient's age, sex, diagnosis, and other test parameters.			
<b>Personnel:</b> Evaluate the effectiveness of policies and procedures for assuring employees' competence in performing testing and reporting test results.			
<b>Communications:</b> If applicable, evaluate documented problems and corrective actions that occur between the laboratory and the authorized individual who orders or receives the test result.			
<b>Complaint Investigation:</b> Evaluate documented complaints and corrective actions.			
<b>Quality Assessment Reviews with Staff:</b> Document discussion with Staff regarding identified problems and corrective actions during the QA review.			