Quarterly QA CHECKLIST

_____ to _____, 20____

Review all items below for the previous quarter, unless otherwise noted. Mark Y (Yes), N (No), or N/A (Not Applicable) and date. Indicate any concerns on the line or back or supplemental pages of this form. Upon completion provide to the Laboratory Director for review.

General Laboratory Systems

Our **Safety and Environmental Policies** were followed:

_____ Was any situation that affected the laboratory safety or compromised employee safety reported to the laboratory director?

Review Safety Anomaly Log

_____ Were all laboratory safety breaches corrected and new safety policies implemented?

_____ Were all testing materials stored as directed by the manufacturer, and all outdated, deteriorated, or incorrectly stored materials discarded and not used for patient testing?

_____ Check **Maintenance Log**: Were all maintenance checks completed and documented as acceptable?

_____ When maintenance or function checks were out of the acceptable range, was corrective action taken, checked for effectiveness, and documented?

Our **Personnel Policies** were followed:

_____ Have all testing analysts read and acknowledged all Lab Manuals? If any revisions have been made, have all affected personnel been made aware of them?

Manual	Yes/No	Comments
Clinical Procedure		
Quality Assurance		
Safety		
Maintenance		

_____ Are all testing personnel evaluated at six months after beginning patient testing and then at least annually thereafter?

_____ Has the training been documented on the Competency Assessment Forms?

Are actual observations noted on the forms?

_____ If personnel competency problems were identified or observed, was corrective action instituted to assist employees to improve performance and evaluated later to ensure the corrective action was effective?

_____ Check the **Communication Log**. Are entries noted?

Our **Proficiency Testing Policies** have been followed:

_____ Were PT samples tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. i.e., the same number of times, using the same personnel and methods as for patient testing, during clinic hours?

_____ Are PT results available for two years after the test event report was received?

_____ Check PT Event Report: Were PT results less than 80% and ungraded PT results (due to lack of consensus, nonparticipation, or late return of results) investigated and findings documented?

Test	Score	Comments

_____ If corrective action was taken, has the problem been corrected over time? If not, have reasons for failure of corrective action been evaluated and a new plan of corrective action formulated and all activities documented?

Our **Preanalytic Systems** were followed as written:

_____ Were patient specimens collected and handled according to our protocol and were they acceptable for testing?

_____ Check **Lab Testing Logs**: Are specimens logged correctly (ensure all patient records contain all required fields, i.e. Unique ID, Last Name, Patient number, result, initials, etc).

Log	Specimens logged correctly (Yes or No)	Comments
Pregnancy		
CT/GC NAAT		
Syphilis		
HIV/Hep C		
STAT lab log		
GC Culture		
Lead		

_____ Check **Lab Orders and Results Log**:

Were any specimens rejected by the lab due to mislabeling, inappropriate or degraded samples or incorrect storage?

_____ Were all specimens positively identified and optimum sample integrity maintained from collection throughout the testing process?

_____ Were all equipment and reagents prepared in a cleaned and sanitized manner. Review autoclave cleaning, autoclave and oven logs.

Our **Analytic Systems** were followed as written:

_____ Check **Temperature Chart**. Were daily temperature checks of refrigerators, incubators and room documented?

_____ When temperature checks were out of the acceptable range, was corrective action taken, checked for effectiveness, and documented?

_____ Check all QA/QC logs, ensure all required fields are completed (for example actual t temperature, initials, dates, ranges, etc.). Were calibration/function checks performed and documented as needed on daily QC log (Example rotator)?

QC Log	Completed as above (Yes or No)	Comments
Lead		
Media Logs		
Wet Prep		
Oxidase		
RPR		
Gram Stain		
hCG QC		
HIV QC		
API NH/Zym B		
Microscope		
APTIMA		

_____ All reagents, controls and calibrators are within the proper dating. Outdated materials were never used for testing patient specimens and were discarded.

_____ Check **QC Log and QC Printouts**:

Were QC samples tested according to our written policies and the manufacturer's instructions?

Have all testing personnel performed QC on a rotating basis?

Were QC results within acceptable limits before patient samples were reported, and was any required corrective action documented?

Were all new lot numbers of QC materials verified before use?

Our **Postanalytic Systems** were followed:

_____ Was confidentiality of all patient information maintained?

_____ Were all complaints and communication problems handled by the lab director or supervisor and documented when deemed necessary?

_____ Were all biohazardous materials handled in accordance with regular procedures. Review Bio waste recording logs.

_____ Were test reports released to authorized persons only?

_____ If an incorrect patient test result was reported, did the laboratory notify the authorized individual (usually the nurse who collected the test) of the correction and submit a corrected report? Are both original and corrected reports kept for two years?

_____ If communication problems developed concerning testing or reporting patient specimens, did the laboratory director or supervisor solve the problem? Attach written report to this **QA Checklist**.

_____ Did lab personnel document all complaints and problems reported to the laboratory by patients, staff members, or others, and did the laboratory director or supervisor request an investigation into complaints and problems, when appropriate? Attach written report to the **QA Checklist**.

Chart Review

_____ Review all patient tests for a minimum of three clinic testing days and ensure results reported on patient logs match results reported in computerized reporting system?

List clinic dates reviewed and any discrepancies identified that were not already documented:

Our **Quality Assessment Program** is monitored quarterly for compliance:

_____ The above information has been reviewed to determine whether errors that occurred could have been prevented by changing our policies or procedures.

_____ Any newly-instituted policies and procedures have been reviewed for effectiveness and communicated to the appropriate employees.

If you answered "No" to any of the above, explain the problem and how it was resolved either in the section or on the next page. Use the back of the page if more space is required. Also, explain any changes made to the laboratory policies and procedures as a result of this Quality Assessment program. Describe any corrective actions taken during the previous month and describe how changes have improved quality of the testing process. Also, describe how pertinent staff was involved in this quality assessment process (discussions or active participation).

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ACTION ITEMS: List all action items below and indicate if any remain from the prior quarter's list.

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Date: _____ Reviewer:_____

Date: _____ Laboratory Director: _____