Quality Assurance Assessment

Write one of the following notations for each item: **Y** (Yes), **N** (No), or **N/A** (Not Applicable)

LABORATORY SAFETY POLICIES were followed:

		Helpful Hints/Notes
	Our lab director was notified of any situation that could affect the System performance.	*Did something unusual occur, such as the instrument was dropped? A prolonged power failure occurred? If nothing unusual occurred, mark "NA".*
	Our lab director was notified of any situation that could affect the safety of testing personnel.	*Did a needle stick or splash to non-intact skin occur? If no safety issues arose, mark "NA".*
	All new laboratory personnel have read the safety guidelines in this manual.	*If no new employees began testing this month, mark "NA".*
	Immunization against Hepatitis B has been offered to all new testing personnel.	*If no new employees began testing this month, mark "NA".*
	Food and drink are not kept in the laboratory refrigerator where FastPacks, controls, calibrators, buffers and method verification kits are stored.	*Check the refrigerator for employee food or drink. Mark "N" if food or drink are found and indicate how it will be corrected in the "Corrective Action Log".*

Our PERSONNEL POLICIES were followed:

	All personnel who perform tests have documented training for these tests.	*If no new employees began testing this month, mark "NA".*
	All personnel who perform tests have read the procedure manual for those tests.	*If no new employees began testing this month, mark "NA".*
	Competency Assessments were performed as required.	*Remember to use the Competency Assessment to evaluate personnel. This must be done 6 months after initial training and then annually from original training date*
	No personnel competency problems were identified or observed.	*If personnel competency problems exist, retrain employees and document this information on the FastPack Training Checklist.*

Our PROFICIENCY TESTING POLICIES have been followed:

	Proficiency tests were handled in the same manner as patient specimens.	*If PT samples were tested exactly like patient samples, mark "Y". If unusual circumstances occurred, mark "N", and explain on the next page. If PT samples were not tested this month, mark "NA".*
	Proficiency test results were evaluated, failures were investigated, and remedial action was taken.	*If PT was satisfactory, mark "Y". If PT failure occurred, attach a copy of the PT Checklist to this QA Assessment. If PT results were not received this month, mark "NA".*

Our PRE AND POST ANALYTIC SYSTEMS were followed as written:

	Patient specimens were collected and handled according to our protocol.	*If any unacceptable samples were received, mark "N" and explain how it will be corrected in the "Corrective Action Log".*
	All lab reports contain correct information.	*Randomly check a few patient charts to be sure the FastPack label is present and contains the patient name/ID# and the operator's initials.*

Quality Assurance Assessment

Write one of the following notations for each item: **Y** (Yes), **N** (No), or **N/A** (Not Applicable)

Our QUALITY CONTROL POLICIES were performed as specified:

		Helpful Hints/Notes
	Each day, all environmental elements are checked, logged and are within normal ranges.	Use your Environmental Log to record temperature conditions for the FastPacks. Record the room temperature and relative humidity of the testing area.
	Each QC Event, two levels of quality control were tested and were within acceptable ranges before patients were tested.	Check the Label Record for completeness. If a QC Event was missed or didn't fall in the correct range on a day that patient tests were run, mark "N" and explain how it will be corrected in the "Corrective Action Log".
	The System is calibrated when there is a change in FastPack lot, or calibration has expired.	Check the Label Record for completeness. If this requirement was not performed, mark "N" and explain how it will be corrected in the "Corrective Action Log".
	Any necessary troubleshooting was performed and documented.	Document all instrument maintenance or troubleshooting that was performed in the "Corrective Action Log".
	The System is operating optimally.	Did a problem occur where Qualigen System Support was notified? If so, document this information in the "Corrective Action Log".

Our QUALITY ASSURANCE PROGRAM is monitored for compliance:

	No complaints or communication problems occurred this month.	If a problem occurred, document the information in the "Corrective Action Log".
	The above information has been reviewed to determine whether errors that occurred this month could have been prevented by changing policies and/or procedures.	Look at the areas where you marked "N". Can you think of ways to prevent these problems from happening again? If so, describe below. Then, change the procedure(s) in the QA Manual to reflect the changes made in the "Corrective Action Log".
	Any newly instituted policies and procedures have been reviewed for effectiveness.	If procedures were not changed this month, mark "NA".

Our MAINTENANCE PROGRAM is performed as specified:

	Wipe down the inside of the analyzer door with a disinfectant wipe on a daily basis.	

If you answered "No" to any item, use the Corrective Action Log to explain the problem and how it was resolved. Also, explain any changes made to laboratory policies and procedures as a result of this assessment. Describe any corrective actions taken and how changes have improved the quality of the testing process. Also, note how staff members were involved in this process.

If changes are made to this Quality Assurance Manual, cross out the old policies and insert the new one(s). Initial and date the change. Have all testing personnel read the change and initial the Quality Assurance Manual Approval form.

Date	Test Analyst	Laboratory Director