Garnet Health	POLICY LEVEL	Page 1 of 2
APPLIES TO:	**CATEGORY:**	**DOCUMENT CONTROL NUMBER:**

Title:
LABORATORY POLICY INSTRUCTIONS

Attachments: **A.**		

Purpose:
One to two sentences only, describes the overall intent of this policy.

Definitions:
Provide definition of terms that are not understood by the majority of readers.

Policy:
Brief paragraph or two summarizing how the Lab handles this subject. Include any clinical significance. Detail for ***how*** *we do this is addressed in the procedure, or work instructions section.*

Think like an inspector reading the policy; the policy should be clear about how we handle a particular process.

Specimens: *Include type, collection, container type, patient preparation, labeling, preservative, storage, transportation, processing, acceptability and rejection criteria, time limit for accepting additional testing, referral testing requirements, specimen interfering substances (such as lipemia, etc.), how specimen rejects are reported to ordering department (re-draw, RDE, etc.).*

Equipment/Reagents/Materials: *List all equipment, slides, solutions, stains, reagents, QC material, calibrators, and consumables needed to perform the test. Include a statement that all equipment, reagents, and controls are used according to the manufacturer's instructions.*

Reagent and Material preparation/Stability/Storage/Expiration: *Describe how reagents, etc., are prepared, labeled, stored, how long they are good for, expiration, etc.*

Environmental Requirements: *List any temperature or humidity requirements, limiting contamination for molecular procedures during specimen prep and testing, as well as how to decontaminate work areas.*

Operational and Preventative Maintenance Checks of Instruments and Equipment: *List all daily, quarterly, annual, as needed maintenance checks. How often PMs are done. BioMed involvement, vendor involvement, etc.*

Safety Requirements: *Biosafety, chemical, biohazardous warnings, radiologic, PPE needed, SDS required, disposal*

Standard(s):
NYSDOH, DNV, AABB, and/or CAP, section only, not specific regulation #

Reference(s):

Include books, manuals, package inserts, journal literature, websites, etc.. Each time you review/revise a policy, you should try to look for more recent literature within the past 5 years. Best practice may have changed. If citing standard documents that are updated frequently, use current edition.

Procedural Steps, these MUST be included in all work instruction attachments, if a particular step is not used it must still be listed but N/A may proceed the listing:

Calibration and Calibration Verification Procedures: include performance parameters (frequency, how to perform, and other details). Include specs for accuracy, precision, sensitivity, and specificity. Include acceptability requirements and corrective action to take when calibration results do not meet acceptability criteria. Include who reviews results.
Quality Control Procedures: include performance parameters (frequency, how to perform, other details). Include Linearity Validation testing performance parameters. Include specs for accuracy, precision, sensitivity, and specificity. Include acceptability requirements and corrective action to take when quality control results do not meet acceptability criteria. When QC is to be repeated and when a re-calibration is to be performed. Include who reviews results.
Test Performance Steps: include step by step explanation of how to perform the test. Include if and when confirmatory testing is required and how it is performed (even if referred out).
Microscopic Examination: include how slides are prepared and how to detect if the slide is inadequately prepared.
Calculations: include any calculations or formulas used to determine the result, and how they are periodically verified.
Interpretation of Results: include visual interpretations, use of flags, rules, etc.
Analytical Measurement/Reportable Range: linearity of analyzer's range, when dilution is needed, etc.
Reference Ranges/Normal or Expected Results/Values: include gender, age, etc.
Critical Ranges: include critical values and how they are communicated.
Reporting Results: include how resulted in EMR, include if autovalidation is used or not.
Limitations: limitations of procedure or methodology, including interfering substances (if specimen related, describe above in Specimen section).
Downtime or Inoperable Test System: describe what happens when system is down (IT or analyzer), test becomes unavailable (out of reagent), including corrective action (who gets notified and how) and alternative plan (send to Catskill, etc.). When you involve Laboratory Medical Director.

Author/Title:
Name of Manager/Supervisor

Approver/Title:
Nader Okby, MD, Laboratory Medical Director

Concurrences

Lab Managers/Supervisors – *if Lab policy*	**CNO –** *if nursing involved send to Lisa Oldham or Boomer Bojo*
Laboratory Director	**CIO** *send to Craig Filipini*
Administrator of Quality, Accreditation & Regulatory Compliance – *Kelly Roth*	**Med Exec Committee –** *per Medical Director discretion*
Other departments as needed, i.e. Pharmacy, DI, etc.	

Document Control

Status Key:		**A** = New	**B** = Reviewed **+ #**	**C** = Revised **+ #**	**D** = Archived
Status	**#**	**Description of Change**		**Date**	**Author/Title**
A	0	Revised to reflect DNV ISO Standards		**(Now)**	**(You)**
C	1	Next time policy is revised; describe revision			