



- Germantown Emergency Center
- Shady Grove Medical Center
- Washington Adventist Hospital

Planned Deviation Documentation

Procedure:	Dimension Vista Calcium		
Reason for Deviation:	<p>Calcium QC is consistently out of range despite troubleshooting (EG: changing reagent lot, calibrating with new calibrator, etc.).</p> <ul style="list-style-type: none"> Correlation studies spanning the range were performed and acceptable at TEA/4. QC matrix known issue per vendor. QC is in high demand and short supply during pandemic and vendor is unable to replenish supply with a new lot. <p>On 11/6/20 @ 5:45 AM, management was notified that Calcium QC was out on all 3 Chemistry analyzers, specifically the high level (acceptable range: 11.9 – 13.7 mg/dL).</p> <ul style="list-style-type: none"> 2 previously analyzed samples (one high, one low) were pulled from when QC was within range and were run on all three Vista analyzers. TEA/4 was acceptable for high and low samples; this demonstrated instrument performance is acceptable to use for patient testing until QC matrix problem can be resolved. <p>Lab to utilize previously tested material as Quality Control to verify instrument performance until an alternative QC material is available. (EG: If only high Calcium QC is out, then one previously analyzed high Calcium patient will be analyzed to verify instrument performance.)</p> <p>The Unassayed Chemistry QC material currently used at GEC may be evaluated as a potential backup until the issue is resolved. See next page</p>		
Medical Director or Designee:	<i>Refer to electronic signature</i>		Date:
Supervisor:			Date:
Deviation Start Date:	11/6/20 @ 6:00am		Deviation End Date: TBD
Testing Personnel Signatures	Start Deviation Signatures		End Deviation Signatures
Printed Name / Tech Code	Signature	Date	Signature
			Date
<i>Review and acknowledgment of this change is electronically documented via MTS</i>			

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The following QC material is currently being used

6.1 Controls Used

Controls	Supplier and Catalog Number
<u>Liquichek™ Unassayed Chemistry Controls</u> Levels 1 and 2	Bio-Rad Laboratories Cat. No. 691 and 692

6.2 Control Preparation and Storage

Control	<u>Liquichek Unassayed Chemistry Controls, Level 1 and 2</u>
Preparation	Allow the frozen control to stand at room temperature (18-25°C) until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer) Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.
Storage/Stability	Thawed: stable for 15 days at 2-8°C. Frozen: stable until the expiration date at -20 to -70°C.