



x Germantown Emergency Center  
 x Shady Grove Medical Center  
 x White Oak Medical Center

### Planned Deviation Documentation

Procedure:	Qualitative hCG by CenMed Elite Plus (SGAH.U09)			
Reason for Deviation:	<p>Instructions for use state:</p> <p><b>Urine Specimen:</b> The results should be read at 3-5 minutes. However, positive result may be read and reported as early as 1minute, but negative result must be reported at 3 minutes only. DO NOT interpret the result after 5 minutes past the addition of the sample.</p> <p><b>Serum Specimen:</b> The results should be read at 5-8 minutes. However, positive result may be read and reported as early as 1minute, but negative result must be reported at 5 minutes only. DO NOT interpret the result after 8 minutes past the addition of the sample.</p> <p>Recently, a young woman required an X-ray in the Emergency Department. The urine hCG was tested on the CenMed Elite Plus test. At 3:00 minutes, the test was negative, and the result was reported. The patient was sent for X-ray based on this negative hCG result. At 3 minutes and 30 seconds, the test turned positive. The Beta HCG Quant result (107 mIU/mL) confirmed that the young woman was indeed pregnant with a gestational age of 1-2 weeks.</p> <p>The cutoff for the CenMed Elite Plus test is 25 mIU/mL and is validated to be 98% accurate at this concentration. A complaint has been logged with the manufacturer to investigate the false negative result at 3:00 minutes. CenMed has been asked to clarify the language / intent of use for the CenMed Elite Plus hCG One Step Urine/Serum Pregnancy Test because it is unclear.</p> <p>The SOP will be changed to state:</p> <ul style="list-style-type: none"> <li>• Urine hCG samples may be read at 3-5 minutes, but all negative results MUST be confirmed by reading the cassette at 5 minutes, prior to releasing the result.</li> <li>• Serum hCG samples may be read at 5-8 minutes, but all negative results MUST be confirmed by reading the cassette at 8 minutes, prior to releasing the result.</li> </ul> <p>Technical staff will be re-trained on the change via MTS.</p>			
Medical Director or Designee:	Dr. Nicolas Cacciabeve – <i>electronic signature</i>		Date: 4/8/21	
Supervisor:	Hollie Genser		Date: 4/8/21	
Deviation Start Date:	4/8/21		Deviation End Date: TBD	
Testing Personnel Signatures	Start Deviation Signatures		End Deviation Signatures	
Printed Name / Tech Code	Signature	Date	Signature	Date
	<i>To be captured electronically via MTS</i>			