Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0192921	08/25/2020
Name of Provider or Supplier	**Street Address, City, State**	
Gmg Tunkhannock	809 Hunter Hwy, Tunkhannock, PA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manuals, personnel competency assessment records and interview with the technical supervisor (TS) and quality coordinator, the laboratory failed to follow their competency assessment program to assess the competency for 3 of 3 TP performing manual differential examinations in 2018 and 2019 and for 1 of 2 consultant/supervisors for their regulatory responsibilities in 2019. Findings Include: 1. The Competency Assessment Program Policy states, #3. "Each non-waived method/instrument platform must include all six elements of competency in the assessments" , and #7. "The performance of delegated section directors/technical supervisors general supervisors and clinical and technical consultants must be assessed annual." 2. On the day of survey, 08/25/2020, the TS and quality coordinator could not provide documentation of competency assessments performed annually for 1 of 2 TS's (also listed as the technical consultant and general supervisor) for their regulatory responsibilities in 2019. 3. The labortaory could not provide competency assessments for 3 of 3 testing personnel performing manual differential examinations that include all six elements of competency in 2018 and 2019. 4. The TS and quality coordinator confirmed the findings above on 08/25/2020 around 9:15 am.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, and interview with the technical supervisor (TS) and quality coordinator, the laboratory failed to document QC for urine sediment microscopic examinations and manual differentials each day of patient testing separately from 03/21/2018 to the day of survey. Findings Include: 1. On the day of survey, 08/25/2020, review of urine sediment microscopic examinations and manual differentials QC records revealed, visual QC's were performed for both tests on the same sheet each day of patient testing. 2. The TS could not differentiate which days QC's were performed for urine sediment microscopic examinations and or for manual differentials examination in 2018, 2019 and 2020. 3. In 2018 (03/21/2018 to 12/31/2018): - 1,005 Urine Sediment Microscopic examination were analyzed. - 378 Manual differentials examination were analyzed. 4. In 2019 (01/01/2019 to 12/31 /2019): - 1,015 Urine Sediment Microscopic Examination were analyzed. - 381 Manual differentials examination were analyzed. 5. In 2020 (01/01/2020 to 08/25 /2020): - 382 Urine Sediment Microscopic Examination were analyzed. - 252 Manual differentials examination were analyzed. 6. The TS and quality coordinator confirmed on 08/25/2020 around 10:00 am.