Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2080285	07/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gwv E Mountain Specialty Clinic	1155 East Mountain Boulevard, Wilkes Barre, 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 of review of laboratory's Competency Assessment Program Policy and interview with the Technical Consultant (TC) #1, the Quality Systems Coordinator and a MT Tech Expert, the laboratory failed to assess the competency of All (6 of 6) testing personnel, responsible for Potassium hydroxide (KOH) and Scabies slide reading in 2017. Findings include: 1. Review of the laboratories Competency Assessment Program Policy, states in section 2: a- 2.1 " The Technical/ Analytical /Preanalytical Specialist/ MTII/ Supervisor or designee monitors and documents competency assessment activities for the employees in their respective areas". b- 2.2 " Following documentation training, employees will be tested for competency twice in the first year of service for each non-waived testing platform. c- 2.3 "After an Employee has perform duties for one year, competency is assessed annually for the procedures they perform. 2. On the day of survey,07/17/2018, the laboratory could not provide documentation of competency assessment records for 6 of 6 TP who perform non- waived KOH and scabies slide readings in 2017. 3. In 2017, 37 KOH patient samples were read onsite. 4. The TC confirmed the findings above on 07/17/2018 around 09:20 am. *** Repeat Deficiency from 09/28/2016 Inspection
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 records and interview with the Technical Consultant (TC) #1, Quality Systems Coordinator and a MT Tech Expert, the laboratory failed to document quality control at least once each day of testing for Potassium hydroxide (KOH) and Scabies Slide reading from September 29, 2016 to July 17, 2018 (23 of 23 months). Findings include: 1. On the day of survey, 07/17 /2018, review of KOH and Scabies quality control records revealed that the laboratory failed to document quality control, at least once each day of testing for KOH and scabies from: a) 4 of 4 months in 2016 (September 29,2016 to December 31, 2016) b) 12 of 12 months in 2017 (January 1, 2017 to December 31, 2017) c) 7 of 7 months in 2018 (January 1, 2018 to July 17, 2018) 2. In 2016, 9 KOH patient samples and 1 Scabies specimen were read onsite. 3. In 2017, 37 KOH patient samples were read onsite. 4. In 2018, 18 KOH patient samples and 1 Scabies patient sample were read onsite. 5. TC #1 confirmed the findings above on 07/17/2018 around 10:35 am.