Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0887433	02/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Hanover Pediatrics	217 Broadway, Hanover, 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 manual and interview with the medical assistant, the laboratory failed to establish a competency assessment policy to assess the competency of 3 of 4 clinical consultants (CC) from 2017 to the day of survey. Findings Include: 1. On the day of survey, 02/26/2020, the laboratory failed to provide a competency assessment policy to assess the competency of 3 of 4 CC from 12/06 /2017 to 02/27/2020. 2. The medical assistant confirmed the finding above on 02/27 /2020 around 09:45 am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the medical assistant, the laboratory failed to perform maintenance protocols for 1 of 1 Sanofi Pasteur Fisher thermometer used to monitor temperatures of the incubator used for throat and urine cultures from 2018 to the day of survey. Findings Include: 1. On the day of survey, 02 /27/2020, observation of 1 of 1 thermometer, used to monitor the temperature of the

	incubator revealed, the thermometer was due for maintenance on 02/04/2015. 2. In 2018: 3,586 throat cultures and 649 urine cultures were examined. 3. In 2019: 3,574 throat cultures and 596 urine cultures were examined. 4. The medical assistant confirmed the findings above on 02/27/2020 around 11:30 am.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (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 medical assistant, the laboratory failed to check and document each batch or shipment of media for sterility, its ability to support growth, select or inhibit specific organisms, and/or produce a biochemical response (end user QC), from 2017 to the date of survey. Findings Include: 1. On the day of survey, 02/27/2020, review of QC records revealed, the laboratory did not perform end user QC on the following media's used for throat and urine cultures from 12/06/2017 to 02/27/2020: - Health Link Streptococcus Selective Agar. - BD BBL Group A Select Agar. - Try Biological Inc, Uricult CLED/EMB media. - Orion Diagnostica Uricult CLED/EMB media. 2. In 2018: 3,586 throat cultures and 649 urine cultures were examined. 3. In 2019: 3,574 throat cultures and 596 urine cultures were examined. 4. The medical assistant confirmed the findings above on 02/27/2020 around 11:00 am.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records, review of the American Proficiency Institute (API) 2018 and 2019 proficiency testing (PT) attestation sheets, and interview with the medical assistant, the TC (laboratory director) failed to assess the competency of 4 of 7 TP through external throat and urine culture PT or internal blind testing samples in 2018 and 2019. Findings Include: 1. On the day of survey, 02/27/2020, review of TP records and API PT attestation sheets revealed, the laboratory director did not assess the test performance of 4 of 7 TP through external throat and urine culture PT samples or internal blind testing samples in 2018 and 2019 for the following personnel: - 2018: CMS 209 Testing Personnel Form - TP #2, 3, 4 and 7. - 2019: CMS 209 Testing Personnel Form - TP #1, 2, 3 and 4. 2. The medical assistant confirmed the finding above on 02/27/2020 around 10:00 am.