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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D0714542 | (X3) Date Survey Completed 03/20/2018 |
| Name of Provider or Supplier Honesdale Pediatric Center | Street Address, City, State 1837 Fair Ave, Honesdale, 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 |
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| D5477 | <p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Selective Strep Agar (SSA) quality control records and personnel interview with the Nurse Manager, the laboratory failed to check and document each batch or shipment of Health Link SSA media for sterility, its ability to support growth, select or inhibit specific organisms or produce a biochemical response, from 2016 to the date of survey. Findings Include: 1. On the day of survey, 03/20/2018, it was discovered that the lab did not perform end user quality control to check if the Health Link SSA media inhibits specific organisms used for throat cultures in 2016 and 2017. 2. In 2016 roughly 1350 throat culture specimen were performed. 3. In 2017 roughly 1363 throat culture specimen were performed. 4. The Nurse manager confirmed the findings above on 03/20/2018 around 10:00 am.</p> |
| D6051 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>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.</p> |

This STANDARD is not met as evidenced by:

Based on, the review of competency assessment records, proficiency testing (PT) records and interview with the Nursing manager, the Technical Consultant failed to assess the competency of all TP through internal blind testing samples or external PT samples for reading throat cultures in 2016 and 2017. Findings Include: 1. At the date of survey, 03/20/2018, review of personnel competency assessment records revealed the laboratory did not assess test performance of TP through internal blind testing samples or external PT samples for 8 of 10 providers reading throat cultures in 2016 and 2017. 2. In 2016 roughly 1350 throat culture specimen were read. 3. In 2017 roughly 1363 throat culture specimen were read. 4. The Nursing Manager confirmed the findings above on 03/20/2018 around 09:30 am.