| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 39D0205215 | 08/29/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| David O'Rourke Md Laboratory | 560 Van Reed Road Suite 306, Wyomissing, 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** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(4)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on by review of the quality control records and personnel interview with the Laboratory Director and Medical Assistant, the laboratory failed to check each batch or shipment of media before or concurrent with initial use, for its ability to support growth from (11/02/2017 through 08/29/2019). Findings: 1. Review of the quality control records revealed ability to support growth was not documented for Hardy Diagnostics Tri Plate media, from (11/02/2017 through 08/29/2019). 2. Approximately 69 patients had urine cultures performed from (09/01/2018 through 08/29/2019). 3. During the survey (11:00 12/13/2016), the Medical Assistant confirmed the above findings. |
| **D6019** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iv)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed |

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| | when any proficiency testing results are found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality control records and interview with the Laboratory Director and the Medical Assistant, the Laboratory Director failed to ensure an approved corrective action plan was followed for urine culture media quality control, from 11/02 /2017 to 08/29/2019. Fidnings include: 1. A plan of correction for urine culture media quality control was approved by the laboratory director, (11/02/2017). 2. The plan of correction specifies urine media control results will be recorded in the urine culture log book. 3. At the time of the inspectiom (09:15 08/29/2019), the laboratory failed to provide urine culture media control results from 11/02/2017 through 08/29/2019. 3. During the inspection (11:08 08/29/2019), the Laboratory Director confirmed that urine culture media quality control, was not documented. See D5477. |