| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D1065839 | 03/06/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Will Richardson Md Pa | 1120 Bayview Dr, Fort Lauderdale, FL | |

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 |
|---|---|
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with Office Manager (OM), the laboratory failed to evaluate the accuracy of the Scabies test, subspecialty of Parasitology and Tzanck test, subspecialty of Virology; at least twice a year for 2 out of 2 (2017 and 2018) years reviewed. For Hematoxylin and Eosin (H&E) slide reading and interpretation, the laboratory failed to verify accuracy in 1 out of 2 (2017 and 2018) years reviewed. Findings include: Review of peer review records, revealed: - No documentation of the peer review for: Scabies and Tzanck tests during 2017 and 2018. - No documentation of 2017 peer review, for H & E slide reading and interpretation for 2017. During an interview on 03/06/2019 at 12:30 PM, the OM confirmed that the laboratory has no documentation of the accuracy verification for the tests of reference during the years reviewed. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on review of quality assurance policy, lack of documentation and interview with Office Manager (OM) the laboratory failed to document the quality assurance (QA) activity for 2 out of 2 years reviewed (2017 and 2018). Findings include: Quality assurance policy stated to perform a monthly review of the overall activity of the laboratory. Review of laboratory records revealed that there was no documentation of the QA activity during the years 2017 and 2018. During an interview on 03/06 /2019 at 11:30 AM, with the OM, she confirmed that there were no records of QA activity for the years of reference. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with Office Manager (OM), the laboratory director (LD) failed to ensure the laboratory follow their QA policy of a monthly Quality Assurance (QA) review for 2 out of 2 years reviewed (2017-2018) Findings include: Review of the Quality Assurance Policy stated that QA review and signed by the LD on a monthly basis. No documentation of the QA for years 2017 and 2018 found during the survey. During an interview on 03/06/2019 at 11:30 AM, with the OM, she confirmed that there were no records of QA activity for the years of reference. |