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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D2141974 | (X3) Date Survey Completed 07/21/2020 |
| Name of Provider or Supplier University Area Community Health Center | Street Address, City, State 13601 N 22nd St, Tampa, 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 |
|---------------------------|--|
| D0000 | An announced CLIA recertification survey was conducted at University Area Community Health Center on 07/21/2020. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies: |
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Medical Laboratory Evaluation (MLE) proficiency testing record review and interview with the Laboratory Director, the laboratory failed to verify accuracy of the yeast and trichomonas vaginalis testing procedure twice annually for two out of two years reviewed (2019 1st, 2nd, and 3rd events and 2020 1st, and 2nd events). Findings included: Record review of the MLE proficiency testing revealed the laboratory performed proficiency testing for yeast one time in 2019 (3rd event) and one time in 2020 (1st event). Additionally, a review of the MLE proficiency testing revealed the laboratory did not perform proficiency testing for trichomonas vaginalis in 2019 and only one time in 2020 (2nd event). On 07/21/20 at 12:10 p.m., the Laboratory Director stated he did not know that the MLE proficiency testing program did not test twice annually for yeast and trichomonas vaginalis.</p> |
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's</p> |

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Director, the laboratory did not follow manufacturer's instructions (MI) for the BD Macro - Vue RPR Card Tests for the required room temperature range for 222 out of 401 days reviewed (October 2018 - July 2020). Findings Included: Review of MI for the BD Macro - Vue RPR Card Tests revealed that the "Immediate use of a refrigerated antigen may result in decreased sensitivity of the test. Therefore, upon removal from the refrigerator, allow the antigen to warm to room temperature (23 - 29 degree Celsius) before use." Review of the "Hillsborough County Health Department STD Laboratory RPR (BD) Indirect Test for Syphilis Quality Control Log" revealed room temperatures were not in the 23 - 29 degree Celsius range on the following days: July 2020 - 4/6 out of range, June 2020 - 6/19 out of range, May 2020 - 6/19 out of range, April 2020 - 12/22 out of range, March 2020 - 11/22 out of range, February 2020 - 14/19 out of range, January 2020 - 13/18 out of range, December 2019 - 10/18 out of range, November 2019 - 6/14 out of range, October 2019 - 11/23 out of range, September 2019 - 16/16 out of range, August 2019 - 20/20 out of range, July 2019 - 19/21 out of range, June 2019 - 13/15 out of range, May 2019 - 19/23 out of range, April 2019 - 4/23 out of range, March 2019 - 7/21 out of range, February 2019 - 7/21 out of range, January 2019 - 6/22 out of range, December 2018 - 1/16 out of range, November 2018 - 11/16 out of range, and October 22 - 31st, 2018 - 6/7 out of range. Interview on 07/21/20 at 12:15 PM with the Laboratory Director revealed he didn't know the MI acceptable room temperature range did not agree with the laboratory's room temperature range on the quality control log.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient test reports and interview with the Laboratory Director, the laboratory failed to have the address of the correct testing laboratory location for 4 out of 4 patient test reports reviewed for 2 of 2 years (2019-2020). Findings Included: Review of 4 patient test reports revealed the patient reports did not have the address of the location where the testing was performed, instead the address was the address of their reference lab. Interview on 07/24/20 at 01:05 PM with the Laboratory Director confirmed that the patient test reports did not have the correct address for the testing location.