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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2011800 | (X3) Date Survey Completed 07/09/2019 |
| Name of Provider or Supplier Brownsville Urgent Care Of Pediatrics Pllc | Street Address, City, State 2050 North Expressway, Brownsville, TX | |
| 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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| 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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory instrument records, and confirmed in interview of facility personnel, the laboratory failed to establish an acceptable room temperature range where the Medonic M-Series hematology analyzer is operated. The findings were: 1. Review of the manufacturer's instructions for the Medonic-M Series hematology analyzer (February 2016, Article No. 1504470) under "Specifications" it stated the operating temperature for the analyzer is "18-32 degrees Celsius." 2. Review of the laboratory's environmental records revealed the laboratory had established its acceptable room temperature as 15-32 degrees Celsius. 3. The findings were confirmed in interview of the technical consultant and laboratory manager on July 9, 2019 at 21:00 hours in the office.</p> |
| D6018 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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</p> |

director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, review of laboratory maintenance records, and confirmed in interview of facility personnel, the laboratory director failed to implement a policy to ensure complete corrective action is performed after a PT failure. The findings were:

1. Review of PT records from 2017 (event 3), 2018 (events 1, 2, and 3) and 2019 (event 1) revealed that for the 1st event of 2018 the laboratory received a score of 47% for WBC Differential (less than 80% is unsuccessful performance).
2. Review of the API Summary revealed that the laboratory had determined through their root cause analysis of the failure, service needed to be contacted. Instrument Service 1 performed maintenance on May 1, 2018. The report stated, "CDS was called to request the Grand-Blood CVP value for QC normal Ctrl Lot #21803-22 Exp. Date 07-31-2018. The CVP value provided was 2.14. adjustment were made. The following day CDS called to go back and re-adjust the CVP values again and ran Proficiency samples after adjustment. 05-03-2018 went back to the account and readjusted CVP value and ran proficiencies. Results were sent to CDS.
3. The laboratory director failed to implement a policy to include patient remediation as part of the corrective action follow-up for a PT failure.
4. An interview with the technical consultant and laboratory manager on July 9, 2019 at 6:45 p.m. in the office confirmed the findings.