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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>45D0966858 | <b>(X3) Date Survey Completed</b><br><br>02/22/2018 |
| <b>Name of Provider or Supplier</b><br><br>Pinnacle Healthcare Pllc DbA Mission Kids Clinic                                | <b>Street Address, City, State</b><br><br>1616 N Conway Ave, Mission, TX   |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | <p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>  |
| <b>D5401</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory policy, review of manufacturer's instructions, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of following its own policy to resolve CBC (complete blood count) results with flags prior to their release to the healthcare provider. The findings were: 1. Review of the laboratory's SOP (standard operating procedure) for resolving flags on the Medonic M Series Hematology Analyzer (no policy title) approved by the laboratory director on June 23, 2017 stated, "Alternate Action: The Auto Diff section exhibiting the flags may be blocked off and not reported. The</p> |

provider will make the assessment of the patient without that portion of the report and only using the hemogram parameters." 2. Review of the manufacturer's instructions for the Medonic M-Series hematology system analyzer (Article no: 1504248, May 2009) stated, ""Abnormalities: Follow your laboratory's protocol for verification on all samples with anomalies and/or abnormal distributions signaled by the instrument. Pathological cells may vary in their stability toward lysing of their cytoplasmic membranes compared to normal cells, which may cause aberrations in the automated analysis. This also applies to the presence of normal non-pathological cells that have been subjected to chemotherapy or other treatments." And, BD - WBC DIFF: high interference between populations: Blood sample too old or pathological sample. Action: Follow laboratory's protocol for verification of results. OM - WBC DIFF: only one WBC population found; slide review advised. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. TM - WBC DIFF: too many WBC populations found; slide review advised. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. 3. Random review of final patient reports from January 2018 retrieved from the laboratory's electronic medical records system on 02/22/2018 revealed the following random review of 4 of 6 patient results that had unverified flags on the CBC report. The flags were not resolved prior to their release to the healthcare provider: a. Sequence # 3606 Date: 01/08/2018 Flag: OM "WBC Diff: Only one WBC population found; slide review advised" b. Sequence #3627 Date: 01/09/2018 Flag: OM "WBC Diff: Only one WBC population found; slide review advised" c. Sequence #3731 Date: 01/16/2018 Flag: BD "BD - WBC Diff: High interference between populations" d. Sequence #3865 Date: 01/24/2018 Flag: OM "WBC Diff: Only one WBC population found; slide review advised" 4. The laboratory was asked to provide documentation of following its own policy to resolve CBC flags prior to the release to the healthcare provider. No documentation was provided. 5. An interview with the primary testing person on 02/22/2018 at 1210 hours in the conference room confirmed the findings. Key: WBC - white blood cell Diff - differential

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(b)(c)

(b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of final patient reports, review of quality assurance reports, and confirmed in interview of facility personnel, the laboratory's quality assurance system failed to identify that flags on CBC (complete blood count) results were not being resolved prior to their release to the healthcare provider. The findings were: 1. Review of the laboratory's policy, "Quality Assurance Program" approved by the laboratory director on September 3, 2014 stated, "Purpose: The purpose of a quality assurance program is to ensure that appropriate patient test management is performed throughout the pre-analytical, analytical and post-analytical phases of testing. This QA program includes test selection, sample collection, transport to the laboratory, analysis, reporting back to the clinician, and final interpretation and decisions making by the clinician ..." 2. Random review of final patient reports from January 2018 retrieved from the laboratory's electronic medical

records system on 02/22/2018 revealed the following random review of 4 of 6 patient results that had unverified flags on the CBC report. The flags were not resolved prior to their release to the healthcare provider: a. Sequence # 3606 Date: 01/08/2018 Flag: OM "WBC Diff: Only one WBC population found; slide review advised" b. Sequence #3627 Date: 01/09/2018 Flag: OM "WBC Diff: Only one WBC population found; slide review advised" c. Sequence #3731 Date: 01/16/2018 Flag: BD "BD - WBC Diff: High interference between populations" d. Sequence #3865 Date: 01/24/2018 Flag: OM "WBC Diff: Only one WBC population found; slide review advised" 3. Review of quality assurance reports from November 2017 to January 2018 revealed the following: January 2018 Approved by laboratory director: 02/16/2018 "QUALITY ASSURANCE: Pre-analytical errors - None Analytical Errors - None Post-Analytical Errors - None Non-Analytical Errors - None" 4. The laboratory was asked to provide documentation of its quality assurance program identifying that CBC reports with flags were not resolved prior to their release to the healthcare provider. No documentation was provided. 5. An interview with the primary testing person on 02/22/2018 at 1210 hours in the conference room confirmed the findings. Key: WBC - white blood cell Diff - differential