

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1061177	(X3) Date Survey Completed 06/16/2022
Name of Provider or Supplier Texas Children's Pediatrics Lone Star	Street Address, City, State 12120 Rr 620 North, Austin, 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
D0000	Noted deficiencies were discussed with the laboratory representative at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy and procedure, patient test reports, interview, and pre-survey paperwork, the laboratory failed to redact or verify flagged indices on the CBC test report using the Medonic M-Series for two out of four flagged patient test reports reviewed. A. Review of the Medonic M-Series User's Manual under 9.2 System Information Messages starting on page 71 stated, "the system software monitors a number of analytical and system functions and will display information that indicates the possible attention of the operator. This information will alert the operator to check the system or sample, or institute selected troubleshooting procedures... System Information Messages... 1. Indicator Message OM WBC Diff: Only one WBC population found; slide review advised. Description There was only one mode in the WBC distribution between the LYM-L and GRAN - H settings. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. 2. Indicator Message TM WBC Diff: Too many WBC population found; slide review advised. Description There were more than two modes in the WBC distribution between the LYM-L and GRAN -H settings. Action Blood sample too old or pathological sample. Follow</p>

laboratory's protocol for verification of results". B. Review of the laboratory's policy and procedure titled CBC Medonic M-Series, revision 08/16, under Procedure Patient Testing- Capillary Draws stated, "7. Report patient testing results. a. It is the responsibility of the Provider to correlate instrument results (including flagged parameters) with clinical findings. See the User's manual (pages 71-76) for system information message descriptions. The Diff flags (BD, NM, OM, and TM) indicate a possible problem with the accuracy of the results. Performing a slide review by a reference lab (as recommended by the manufacturer) or further will be performed as requested by the attending Provider. Don't Report in EMR and mark out with dark line on original." C. Review of 7 patient reports, showed 4 had flagged indices. Of the 4 test reports with flagged indices, 2 had been reported (not redacted). 1. On 12/15/2021, sample at sequence #4432 was flagged with OM for the LYM, MID, GRAN, LYM%, MID%, GRA% and reported. 2. On 12/16/2021, sample at sequence #4442 was flagged with TM for the LYM, MID, GRAN, LYM%, MID%, GRA% and reported. D. Interview with the technical consultant on June 16, 2022 at 1100 hours confirmed testing personnel were not following the procedure and indices with flags were reported. E. Review of pre-survey paperwork showed the annual test volume was 3828. KEY: CBC = Complete Blood Count EMR = Electronic Medical Record LYM = absolute Lymphocytes MID = absolute Monocytes, mixed GRAN = absolute granulocytes LYM% = percent Lymphocytes MID% = percent Monocytes, mixed GRA% = percent Granulocytes