

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0677714	(X3) Date Survey Completed 10/14/2020
Name of Provider or Supplier Kansas Medical Clinic	Street Address, City, State 1261 E Tulsa Avenue, Kansas, OK	
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	The recertification survey was performed on 10/14/2020. The findings were reviewed with the technical consultant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director or designee failed to sign a proficiency testing attestation statement for 1 of 7 events. Findings include: (1) On 10/14/2020, the surveyor reviewed 2019 and 2020 proficiency testing records and identified the following for 1 of 7 events: (a) First 2019 Hematology Event - The attestation statement had not been signed by the laboratory director or designee. (2) The surveyor reviewed the findings with the technical consultant. The technical consultant stated on 10/14/2020 at 02:15 pm, the attestation statement had not been signed by the laboratory director or designee.</p>
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p>

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant, the laboratory failed to participate in 1 of 7 proficiency testing events. Findings include: (1) On 10/14/2020, the surveyor reviewed proficiency testing records for 2019 and 2020 and identified the laboratory attained a 0% score for the analytes Red Blood Cell Count, Hematocrit, Hemoglobin, White Blood Cell Count, Platelet Count, and White Blood Cell Differential, for the third 2019 Hematology Event, due to a failure to participate; (2) There was no documentation in the laboratory records to indicate what occurred for the laboratory to not participate; (3) The surveyor reviewed the records with the technical consultant and asked if corrective action had been documented to explain why the laboratory did not participate in the event. The technical consultant stated on 10/14/2020 at 02:00 pm the following: (a) The laboratory had performed corrective action which included a self evaluation, but the documentation could not be located during the survey.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:
Based on a review of the policy and procedure manual and interview with the technical consultant, the laboratory failed to follow written procedures for CBC (Complete Blood Count) testing for 3 of 9 patient reports. Findings include: (1) On 10/14/2020 at 01:30 pm, the technical consultant stated to the surveyor: (a) CBC testing was performed on the Medonic M-Series hematology analyzer. (2) The surveyor reviewed the written procedures titled, "Medonic Flagged Results Policy", which stated, (a) "WBC Differential results may be flagged BD, NM, OM, and TM If the patient sample is flagged the sample is held for 5-10 minutes and the test repeated. If the flags have been removed or are still present in the same location the results are reported. At the physician's discretion the sample may be referred for further testing."; (b) "If the sample volume is not sufficient for repeat analysis, another sample can be drawn OR the flagged result may not be reported in LabDaq and, if paper printouts are reviewed by the provider, the flagged results must be blacked out completely." (3) The surveyor reviewed 9 patient records that had been tested between January 2020 through May 2020. For 3 of 9 patient records there was no indication the laboratory staff followed their written procedure as follows: (a) Patient tested 03/09/2020 at 05:

32 pm - No evidence the OM flag was repeated; (b) Patient tested 01/04/2020 at 01:57 pm - No evidence the provider reviewed the OM flag; (c) Patient tested 02/14/2020 at 12:30 pm - No evidence the provider reviewed the BD flag. (4) The surveyor reviewed the findings with the technical consultant who stated on 10/14/2020 at 03:45 pm that the procedure had not been followed as indicated above.