

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1052983	(X3) Date Survey Completed 04/19/2023
Name of Provider or Supplier Baxter Regional Crossroads Medical Clinic	Street Address, City, State 1420 Highway 62 65 North Suite 1, Harrison, AR	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Through review of personnel records, lack of documentation and interview with laboratory staff members it was determined that annual (and/or twice annually during the first year of employment) competency determinations were not performed for three of four personnel listed on the CMS 209 form. Findings follow: A) Review of personnel records revealed that no competency evaluations were presented for the laboratory staff member (# 1 on the CMS 209 form) who began employment in the laboratory on January 2022, no competency evaluations were presented for the laboratory staff member (# 4 on the CMS 209 form) and the last competency evaluation presented for laboratory staff member (#5 on the CMS 209 form) was dated in December 2020. B) Upon request the laboratory was unable to produce records of competency assessment performed in 2022 on the staff members identified above. C) In an interview on 4/19/23 at 9:15 a.m., the laboratory staff member (# 1 on the CMS 209 form) stated that she had not had a competency assessment since beginning work in January 2022 and she couldn't find competency records other than those already provided.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a</p>

maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Through review of maintenance records for 2021 and 2022, lack of documentation and interviews with laboratory staff it was determined that the laboratory did not document that required maintenance procedures were performed on the Medonic hematology analyzer in 4 of the 24 months reviewed. Findings follow: A) Review of the required daily, weekly and monthly maintenance documentation forms provided by the manufacturer of the Medonic hematology analyzer revealed that the forms were blank for November 2021 through February of 2022. B) Upon request, the laboratory was unable to provide documentation of maintenance performed on the Medonic hematology analyzer for the period of November 2021 through February 2022. C) In an interview on 4/19/23 at 10:45 a.m., the laboratory staff member (#1 on the CMS 209 form) stated that documentation of maintenance for the Medonic hematology analyzer was not available for November 2021 through February 2022 and the instrument was in use during that period.

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:

Through review of the CMS 116 CLIA application form, observation, interview and review of two randomly selected comprehensive metabolic panel (CMP) chemistry results it was determined that routine chemistry results reports did not contain the name and address of the laboratory performing the tests. Findings follow: A) Review of the CMS 116 CLIA application revealed that no routine chemistry tests were identified as being performed in the laboratory. B) On an initial tour of the laboratory on 4/19/23 at 8:45 a.m., the surveyor observed that there was no test instrumentation capable of performing routine clinical chemistry testing present in the laboratory. C) In an interview on 4/19/23 at 8:45 a.m., the laboratory staff member (# 1 on the CMS 209 form) stated that all routine chemistry testing was referred to their parent hospital in another city. D) Review of CMP final result reports on patient (identified as number 1 on a separate patient identification list) performed on 7/29/22 and patient (identified as number 2 on a separate patient identification list) performed on 3/8/23 revealed the only name and address on the report was the name and address of the clinic being surveyed. E) In an interview on 4/19/23 at 11:30 a.m. the laboratory staff member (# 1 on the CMS 209 form) confirmed that the tests were performed by the referral hospital and the name and address of the lab performing the tests were not on the final report.

D6031**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

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 director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Through review of policy and procedures provided during the survey, lack of documentation, review of CLIA records, review of the CMS 116 CLIA application form, observation, review of patient records and interviews with laboratory staff it was determined that the laboratory director failed to review and approve the laboratory procedure manual and procedures were not available for all testing performed by the laboratory. Findings follow: A) In an initial interview on 4/19/23 at 8:45 a.m., the laboratory staff member (# 1 on the CMS 209 form) stated that the laboratory did not have a policy and procedure manual "that I asked for one and haven't gotten one yet". B) On 4/19/23 at 11:00 a.m., a policy and procedure manual was found that was approved by the previous laboratory director on 8/18/20 and there was no documentation of review and approval by the current laboratory director. C) Review of the CMS 116 CLIA application form provided by the laboratory revealed that wet prep examinations were provided by the laboratory. D) On a tour of the laboratory on 4/19/23 at 10:55 a.m., a microscope, KOH solution, and microscope slide and cover-slips were observed in the office of the laboratory staff member (# 5 on the CMS 209 form). That employee had previously signed the attestation sheet as the testing personnel for all proficiency testing for wet preps reported in 2021. E) Review of patient medical records revealed that a wet prep examination was performed and reported on patient 174365 on 4/17/23. F) Review of the policy and procedure manual revealed that no policy and procedure for wet prep examinations was present in the policy and procedure manual. G) In an interview on 4/19/23 at 11:15 a.m., the laboratory staff member (# 1 on the CMS 209 form) stated there was no policy and procedure for wet prep examinations "they just know how to do it".