

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0027947	<b>(X3) Date Survey Completed</b> 10/02/2023
<b>Name of Provider or Supplier</b> Crossroads Medical Group, PLLC	<b>Street Address, City, State</b> 3500 N Mt Juliet Rd Ste 201, Mount Juliet, TN	
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>
<b>D0000</b>	During a recertification survey on 10/02/2023, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1215 Condition: Hematology 42 CFR 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant 42 CFR 493.1421 Condition: Laboratories performing moderate complexity testing: testing personnel
<b>D5024</b>	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) for moderate and high complexity testing (Form CMS-209), laboratory policies, lack of policies and records, and quality control records, the laboratory failed to follow it's own policy for TP competency assessment (See D5209), failed to follow it's own policy for quality assessment (See D5291), and failed to have corrective action policies and procedures in place (See D5779).</p>
<b>D5209</b>	<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>

This STANDARD is not met as evidenced by:  
 Based on review of the Form CMS-209, laboratory policy, employee records, lack of records, and staff interview, the laboratory failed to follow their own policy for assessing testing personnel (TP) competency for complete blood count (CBC) patient testing in 2021, 2022, and 2023 for eight of eight TP reviewed. The findings include:  
 1. Review of the Form CMS-209 revealed eight TP that performed moderately complex CBC patient testing. 2. Review of the laboratory policy titled "Quality Assurance Program" revealed competency assessments for TP required semiannually during the first year of employment and annually thereafter. 3. Review of employee records revealed hire dates as follows: TP one- 05/2015 TP two- 05/2022 TP three- 06 /2017 TP four- 02/2021 TP five- 01/2023 TP six- 02/2022 TP seven- 08/2022 TP eight- 05/2023 4. Competency assessments were not available on the date of the survey (10/02/2023) for eight of eight TP that performed CBC patient testing in 2021, 2022, and 2023. 5. Interview on 10/02/2023 at 11:00 am with the office manager confirmed the laboratory failed to follow it's own policy for TP competency assessments when competency assessments were not performed for any of the eight TP.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
 CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory policy, lack of records, and staff interview, the laboratory failed to follow it's own policy for quality assurance when reviews were not performed in 2021, 2022, or 2023 of quality control data or patient chart reviews for the Medonic CBC instrument. The findings include: 1. Review of the laboratory policy titled "MONTHLY AND QUARTERLY QUALITY ASSURANCE ASSESSMENT" revealed the laboratory would evaluate CBC quality control monthly, and five random charts would be reviewed on a quarterly basis. 2. Documented quality assessment records were not available on the date of the survey (10/02/2023) for 2021, 2022, or 2023. 3. Interview with the office manager on 10/02 /2023 at 12:40 pm confirmed the laboratory failed to follow it's own policy for Quality Assurance when reviews were not performed for CBC quality control data or patient chart reviews in 2021, 2022, or 2023.

**D5779**

**CORRECTIVE ACTIONS**  
 CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:  
 Based on observation of the laboratory, review of quality control records, lack of records, patient test report review, and staff interview, the laboratory failed to have a policy or procedure in place for corrective action for the Medonic M Series instrument

used for CBC patient testing in 2023. 1. Observation of the laboratory on 10/02/2023 at 10:00 am revealed a Medonic M series (serial #20395) instrument in use for CBC patient testing. 2. Review of the laboratory's quality control records revealed the following out of range analytes: 02/07/2023 QC lot 2221033 red blood cell (RBC) 15.3 (range 15.5-16.5) 06/26/2023 QC lot 2230333 RBC 4.73 (range 4.86-5.30), hemoglobin (Hgb) 15.2 (range 15.7-16.7) and hematocrit (Hct) 43.7 (range 43.8-50.8) 09/12/2023 QC lot 2230633 Hgb 16.0 (range 16.1-17.1) 3. A corrective action policy or procedure was not available on the date of the survey (10/02/2023). 4. Review of patient test records revealed the following CBC patient test reported Patient #1002171 reported 02/07/2023 Patient #1012742 reported 06/26/2023 Patient #1028346 reported 09/12/2023 5. Interview on 10/02/2023 at 12:40 pm with the office manager confirmed the laboratory failed to have a corrective action policy or procedure in place for investigation of failed quality control for the Medonic M series CBC instrument in 2023.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of the Form CMS-209, laboratory personnel records, quality control records, lack of records, patient test reports, and staff interview, the laboratory failed to employ one or more technical consultants that meet the training or experience requirements in subpart M (See D6034), failed to maintain a quality control and quality assurance program to ensure analytical performance was acceptable (See D6042), and failed to evaluate the competency of testing personnel (See 6046).

**D6034**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:  
Based on review of the Form CMS-209, laboratory personnel records, and staff interview, the technical consultants listed on the Form CMS-209 did not meet the training or experience requirements in Subpart M for performing technical consultant duties. The findings include: 1. Review of the Form CMS-209 revealed two technical consultants listed for moderately complex hematology testing. 2. Review of the laboratory personnel records revealed lack of laboratory training or experience to provide technical consultation for CBC patient testing on the date of the survey (10/02/2023). 3. Interview with the office manager on 10/02/2023 at 11:00 am and phone interview on 10/03/2023 at 3:07 pm confirmed the technical consultants listed on the Form CMS-209 did not have documentation of the required laboratory training or

experience necessary to qualify as a technical consultant and provide technical oversight of patient testing for CBC.

**D6042**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review review of the laboratory's quality control and calibration records, lack of records, and staff interview, the technical consultant failed to ensure the laboratory quality control and quality assurance plan was maintained for the Medonic M Series CBC instrument in 2021, 2022, and 2023 (Refer to D5291 and D5779). 1. Observation on 10/02/2023 at 10:00 am of the laboratory revealed a Medonic M Series (Serial #20395) instrument in use for CBC patient testing. 2. Review of the laboratory quality control records revealed dates where QC was not within the laboratory's range with no corrective action performed (Refer to D5779). 3. Review of the laboratory's calibration records revealed the technical consultant had not reviewed three of three calibrations performed (12/10/2021, 12/22/2022, and 06/16/2023). 4. There was no documented quality assurance reviews of the CBC quality control performed in 2021, 2022, or 2023 (Refer to D5291). 5. Interview on 10/02/2023 at 12:40 pm with the office manager confirmed the technical consultant failed to ensure the laboratory's quality control and quality assessment programs for the Medonic M Series CBC instrument was maintained in 2021, 2022, and 2023, when there was no QC corrective action plan, calibrations had not been reviewed, and the quality assessment plan was not followed.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's testing personnel records, lack of documentation, and staff interview, the technical consultant failed to ensure testing personnel were trained and evaluated for use of the Medonic M Series CBC instrument (Refer to D5209). The findings include: 1. Review of the laboratory's testing personnel records revealed eight testing personnel who perform patient testing for CBC. 2. There was no documented competency for any of the eight testing personnel on the date of the survey (10/02/2023). 3. Interview on 10/02/2023 at 12:40 pm with the office manager confirmed that none of the eight testing personnel had documentation of competency assessment for use of the Medonic M Series CBC instrument.

**D6063**

**LABORATORY TESTING PERSONNEL**

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the Form CMS-209, testing personnel record review, and staff interview, testing persons four and eight did not qualify as testing personnel for moderately complexity patient testing due to lack of documentation of highest level of education. (See D6065)

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the Form CMS-209, review of testing personnel records, and staff interview, testing persons four and eight failed to have documentation of highest level of education on the date of the survey (10/02/2023). The findings include: 1. Review of the Form CMS-209 revealed testing persons four and eight (two of eight) listed as performing moderately complex patient testing. 2. Review of testing personnel records revealed there was no documentation of the highest level of education for testing persons four and eight. 3. Interview with the office manager on 10/02/2023 at 11:00 am confirmed that testing persons four and eight did not have evidence of highest level of education for performing moderately complex patient testing in 2021, 2022, or 2023.