

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1007485	<b>(X3) Date Survey Completed</b>  09/27/2023
<b>Name of Provider or Supplier</b>  Newstart Family & Obstetrical Care Llc	<b>Street Address, City, State</b>  3530 Hickory Hill Road, Memphis, 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 09/27/2023, the laboratory was found out of compliance with the following conditions: 42 CFR 493.801 Condition: Enrollment and testing of samples
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Casper Report 0155D (CMS 155), lack of records, patient rest review, and staff interview, the laboratory was not enrolled in proficiency testing (PT) for the regulated White Blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt), and automated WBC differential (WBC Diff) in 2023. The findings include: 1. Review of the CMS 155 revealed no proficiency testing scores for 2023 for the WBC, RBC, Hgb, Hct, Plt and WBC Diff analytes.. 2. Review of the laboratory's proficiency test records revealed none were available for 2023. 3. Review of patient test reports revealed patient reporting for CBC on 03/02/2023 (patient 2556) and 08/24/2023 (patient 79808). 4. Interview on 09/27/2023 at 11:00 am with testing person one confirmed the laboratory did not enroll in PT for the regulated CBC analytes in 2023 with patient testing being performed and reported.</p>

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report CLIA (Form CMS-209), laboratory policy, personnel records, patient test record review, and staff interview the laboratory's testing personnel competency assessment policy failed to include the six required criteria for assessing competency, and failed to ensure the policy included a requirement to re-assess competency when test methodology changes as required in Subpart M. The findings include: 1. Observation of the laboratory on 09/27/2023 at 9:20 am revealed a Medonic M Series CBC instrument (Serial # 49877) in use for CBC patient testing (new since last survey). 2. Review of the Form CMS-209 revealed two testing personnel that performed moderately complex CBC patient testing. 3. Review of the laboratory policy titled "Quality Assurance Program" in section 5 "Personnel Assessment" revealed the policy did not include the six competency assessment criteria or a requirement to re-assess competency when test methodologies or instruments change as required in Subpart M. 4. Review of the laboratory personnel records revealed the following: Competency assessments performed for two of two testing personnel in 2021, 2022, and 2023 did not include direct observation of test performance, monitoring recording and reporting of test results, review of preliminary results, worksheets, quality control (QC), PT, and preventative maintenance, direct observation of instrument maintenance and function checks, assessment of test performance through blind testing or external PT samples, or problem solving skills. Competency assessments were not assessed for two of two testing personnel prior to patient testing for the Medonic CBC instrument in use beginning 06/14/2022. 5. Review of patient test reports revealed the first date of patient testing on the Medonic M Series CBC instrument was on 06/14/2022. 6. Interview on 09/27/2023 at 11:15 am with testing person one confirmed the laboratory failed to ensure the personnel policy included the requirements in Subpart M for competency assessments in 2021, 2022, and 2023. She further confirmed that competency assessments performed for testing persons one and two during the period did not include the required six elements.

**D5407**

**PROCEDURE MANUAL**

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, laboratory procedure review, patient test report review, and staff interview, the laboratory director did not approve, sign, or date the new procedure for the Medonic M Series CBC instrument used for patient testing prior to use in 2022. The findings include: 1. Observation of the laboratory on 09/27/2023 at 9:20 am revealed a Medonic M Series (serial # 49877) CBC instrument in use for patient testing (new since the last survey). 2. Review of the procedure in use

titled " Procedure Manual Boule Medonic M Series Hematology Analyzer" revealed the laboratory director had not approved, signed, or dated the procedure prior to patient testing that began 06/14/2022. 3. Review of patient test report revealed patient testing on the Medonic M Series began on 06/14/2022 (patient # 33413). 4. Interview on 09/27/2023 at 11:15 am with testing person one confirmed the laboratory director failed to approve, sign, and date the procedure prior to use for CBC patient testing in 2022 for the Medonic M Series instrument.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, review of laboratory procedure, calibration records, and staff interview, the laboratory failed to follow the manufacturer instructions for calibration frequency for the Medonic M Series CBC instrument used for patient testing in 2022 and 2023. The findings include: 1. Observation of the laboratory on 09/27/2023 at 9:20 am revealed a Medonic M Series (serial # 49877) instrument in use for CBC patient testing. 2. Review of the laboratory procedure titled "Procedure Manual Boule Medonic M Series Hematology Analyzer" section "Calibration" revealed "Calibration must be performed upon setup of the instrument and then at a minimum of every six months". 3. Review of the laboratory calibration records revealed the following: Calibration performed 06/09/2022 (setup) No record of 6 month calibration due on 12/03/2022 4. Interview on 09/27/2023 at 11:15 am with testing person one confirmed the laboratory failed to perform calibrations according to the manufacturer requirements in 2022 for the Medonic M Series CBC instrument.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:  
Based on review of the CMS 155, lack of records, patient test review, and staff interview, the laboratory director failed to ensure the laboratory was enrolled in an

approved HHS PT program for 2023 for the CBC regulated analytes to include WBC, RBC, Hgb, Hct, Plt, and WBC Diff (See D2000). The findings include: 1. Review of the CMS 155 revealed no PT scores for the regulated CBC analytes for 2023. 2. There were no PT records available for review on the date of the survey (09/27/2023) for 2023. 3. Patient test report review revealed CBC results reported on 03/02/2023 (patient # 2556) and 08/24/2023 (patient # 79808). 4. Interview on 09/27/2023 at 11:00 am with testing person one confirmed the laboratory director failed to ensure the laboratory was enrolled in PT for the regulated CBC analytes in 2023 with patient testing being performed and reported.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, review of personnel records, and staff interview, the laboratory director failed to ensure testing personnel (two of two) were trained prior to patient CBC results reported using the Medonic M series CBC instrument in 2022. The findings include: 1. Observation of the laboratory on 09/27/2023 at 9:20 am revealed a Medonic M series (serial # 49877) instrument in use for CBC patient testing (new since the last survey). 2. Review of the laboratory personnel records revealed the following: The training documents for testing person one for use of the Medonic M Series CBC instrument did not include the laboratory director's signature. There was no documented training for use of the Medonic M Series CBC instrument for testing person two. 4. Interview on 09/27/2023 at 11:15 am with testing person one confirmed the laboratory director failed to review training documents for testing person one to ensure training was adequate, and failed to ensure testing person two received training for use of the Medonic M Series CBC instrument with patient testing that began on 06/14/2022.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on laboratory record review and staff interview, the laboratory director failed to specify in writing the responsibilities and duties of consultants and testing personnel that performed CBC patient testing in 2021, 2022, or 2023. The findings include: 1. Laboratory record review revealed responsibilities and duties of consultants and testing personnel was not available on the date of the survey (09/27/2023). 2. Interview on 09/27/2023 at 11:15 am with testing person one confirmed the laboratory director failed to ensure there were written responsibilities and duties for the testing personnel who perform patient testing for CBC on the date of the survey (09/27/2023).