Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1007485	07/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Newstart Family & Obstetrical Care Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5024	HEMATOLOGY CFR(s): 493.1215 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. This CONDITION is not met as evidenced by: The laboratory failed to follow policy for investigation of unacceptable proficiency testing scores (Refer to D5291), failed to follow manufacturer instructions for calibration (Refer to D5437), and failed to use correct quality control ranges (Refer to D5469).
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 the laboratory's procedure manual, proficiency testing records and interview with the lead testing person, the laboratory failed to follow the policy for evaluation of unsatisfactory proficiency testing results in 2020. The findings include: 1. Review of the laboratory's policy titled "Quality Assurance Plan" revealed the following statement: "We will carefully evaluate any unacceptable, unsatisfactory, or unsuccessful proficiency testing result in an effort to identify the cause of failure." 2. Review of the laboratory's proficiency testing records revealed the following: 2020

	event A for hematology was not submitted on time. Self grade of the proficiency testing scores revealed unacceptable results for White Blood Cell, Lymphocyte %, Monocyte %, Granulocyte %, Red Blood Cell, Hemoglobin, Hematocrit, MCV, Platelet Count and RDW. No corrective action was performed for the unacceptable scores. 3. Interview with the lead testing person on July 19, 2021 at 2:30 pm confirmed the laboratory failed to follow the policy for investigation of unacceptable proficiency testing scores for 2020 event A for hematology.
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 the manufacturer's calibration instructions, the laboratory's calibration records, patient test reports and interview with the lead testing person, the laboratory failed to follow the manufacturer's instructions for performing quality control after instrument calibration in 2019, 2020, and 2021 for four out four calibrations performed. The findings include: 1. Observation of the laboratory on July 19, 2021 at 8:30 am revealed the Beckman Coulter AcT Diff instrument in use for patient testing for complete blood count. 2. Review of the Beckman coulter AcT Diff operator's manual revealed that QC is to be performed after calibration of the instrument for verification of the calibration. 3. Review of the laboratory's calibration records revealed that QC was not run after calibration for calibrations performed on 10.24.2019, 04.24.2020, 11.18.2020, and 07.16.2021. Twelve patients were reported after the calibration on 11.18.2020 before QC was performed the next day. 4. Interview with the lead testing person on July 19, 2021 at 2:30 pm confirmed the laboratory failed to follow the manufacturer's instructions for performing QC after calibration for four of four calibrations performed in 2019, 2020, and 2021.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be

	established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's quality control (QC) records, and interview with the lead testing person, the laboratory failed to verify the control ranges in use for the Beckman coulter AcT Diff in 2020 and 2021 for complete blood count testing (CBC). The findings include: 1. Observation of the laboratory on July 19, 2021 at 8:30 am revealed the Beckman Coulter AcT Diff instrument on the counter in use for patient CBC testing. 2. Review of the laboratory's QC records to include the manufacturer stated limits and the laboratory ranges in use revealed the laboratory used incorrect QC ranges for the following lot numbers: 069600, 079600, 089600-In use from 03.12.2020 to 06.11.2020 068500, 078500, 088500-In use from 09.15.2020 to 12.21.2020 069100, 079100, 089100-In use from 12.22.2020 to 03.15.2021 069900, 079900, 089900-In use from 03.22.2021 to 06.21.2021 068000, 078000, 088000-In use from 06.21.2021 to Current date. 3. Review of patient CBC test records revealed patient testing performed during the period the incorrect quality control ranges were in use for patient number two (04.10.20), number three (09.16.20), number four (01.06.21), and number five (06.30.21). 3. Interview with the lead testing person on July 19, 2021 at 2:30 pm confirmed the laboratory uses the manufacturer stated quality control limits and failed to use the correct quality control limits for the AcT Diff instrument in 2020 and 2021 for 15 out of 18 quality control lots reviewed with patient testing performed.