Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1007485	10/18/2024
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
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 a review of the laboratory procedure manual, the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory personnel records, and staff interviews, the laboratory failed to follow its policy for testing personnel competency for three of three testing personnel (TP) that performed complete blood count (CBC) patient testing in 2023 and 2024. The findings include: 1. A review of the laboratory policy titled "Competency Assessment Checklist" revealed the following: "Key to methods used for competency evaluation: 1. Direct observations of routine patient test performance, including patient preparation specimen handling, processing, testing., 2. Monitor the recording and reporting of test results. 3. Review of intermediate test results or worksheets, quality control records, proficiency test results, and preventive maintenance logs. 4. Direct observations of performance of instrument maintenance and function checks., 5. Assessment of test performance through testing previously analyzed specimens internal blind testing samples, or external proficiency testing samples., 6. Assessment of problem solving skills". 2. A review of the Form CMS-209 revealed three TP who performed patient CBC testing. 3. A review of the laboratory personnel records revealed the following completed competency assessments did not include documenation of direct observation of routine patient test performance (1), review of intermediate test results or worksheets (3), assessment of test performance through previous samples or blind testing (5), or assessment of problem solving skills (6). TP1 The initial competency assessment completed on 10/23/2023. The 6-month competency assessment completed on 04/24/2024. TP2 The initial competency assessment completed on 10/23

	/2023. The 6-month competency assessment completed on 04/24/2024. TP3 The initial competency assessment completed on 10/23/2023. The 6-month competency assessment completed on 04/24/2024. 4. An interview on 10/18/2024 at 12:00 p.m. with testing person one confirmed the laboratory failed to follow its policy for testing personnel competency assessment for three of three personnel who performed CBC patient testing in 2023 and 2024.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 quality control records, lack of records, and staff interviews, the laboratory failed to have a procedure to monitor precision and accuracy over time for the quality control (QC) used for the Medonic M series instrument used for complete blood count (CBC) patient testing in 2023 and 2024. The findings include: 1. Observation of the laboratory on 10/18/2022 at 9:40 a. m. revealed the Medonic M series (serial #49877) instrument used for CBC patient testing. 2. A review of the laboratory's QC records for the Medonic M series revealed the following: Lots 2230901, 2230902, 2230903 used 12/20/2023 Lots 2240131, 2240132, 2240133 used 04/04/2024 Lots 2240631, 2240632, 2240633 used 09/10 /2024 3. A review of the laboratory QC records revealed that the laboratory did not include records that monitor precision and accuracy over time. 3. An interview on 10 /18/2024 at 12:00 p.m. with testing person one confirmed that the laboratory did not have a process in place to monitor the accuracy and precision of the QC used for the Medonic M series for patient testing in 2023 and 2024.