Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1007485	07/23/2026
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records, testing personnel records, patient test records, and a staff interview, the laboratory failed to ensure that two of four testing personnel (testing personnel three and four) participated in proficiency testing in 2025 and 2026. 1. A review of the FORM CMS-209 revealed four individuals who performed patient testing for Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff). 2. A review of the laboratory's WSLH proficiency testing records revealed that testing persons three and four (as listed on Form CMS-209) did not participate in proficiency testing in 2025 or 2026. 3. A review of testing personnel records revealed that testing person three was signed off for initial competency on 03/24/25, and testing person four was signed off for initial competency on 02/20/25. 4. A review of randomly selected patient records revealed patient CBC w/Diff testing performed by testing person three (patient number 75765 on 03/02/26; patient numbers 74545 and 81835 on 05/27/26) and by testing person four (patient number 83747 on 05/27/26). 5. The lead testing person confirmed the survey findings during an interview on 07/23/26 at 1:15 p.m.
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 laboratory observation, a review of the laboratory's testing personnel policy, a review of testing personnel training and competency assessment records, and staff interview, the laboratory failed to establish procedures for training that was in compliance with Subpart M, failed to follow established procedures for competency assessment, and failed to ensure the procedure required competency assessment twice during the first year of patient testing. This was cited on the previous survey from 10 /18/24, and compliance was not maintained. The findings include: 1. Laboratory observation on 07/23/26 at 8:55 a.m. revealed the Medonic M instrument was used to perform CBC w/Diff patient testing. 2. A review of the laboratory's testing personnel policy revealed that the policy did not define elements required for training, or a requirement for competency assessment twice during the first year of patient testing. The 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 observation 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." 3. A review of testing personnel training and competency assessment records revealed the following: The training documentation for two of two new testing persons (three and four) did not include troubleshooting, control procedures, factors that affect test results, review of background counts, and evaluation of quality control data. Testing person three: The initial competency on 03/24/25 did not include assessment of specimen collection and handling, record review, evaluation of problem-solving skills, or assessment of test performance using previously analyzed specimens, internal blind testing, or external proficiency testing samples. The 6-month competency assessment performed on 09/30 /25 did not include assessment of specimen collection and handling, record review, evaluation of problem-solving skills, or assessment of test performance using previously analyzed specimens, internal blind testing, or external proficiency testing samples. The annual competency assessment performed on 03/27/26, did not include assessment of specimen collection and handling, record review, or assessment of test performance using previously analyzed specimens, internal blind testing, or external proficiency testing samples. Testing person four: The initial competency assessment performed on 02/20/25 did not include assessment of specimen collection, record review, evaluation of problem-solving skill, or assessment of test performance using previously analyzed specimens, internal blind testing, or external proficiency testing samples. The six-month competency assessment performed on 08/15/25 did not include assessment of specimen collection, record review, evaluation of problem-solving skills, or the assessment of test performance using previously analyzed specimens, internal blind testing, or external proficiency testing samples. The annual competency assessment performed on 02/25/26 did not include assessment of specimen collection, record review, or assessment of test performance using previously analyzed specimens, internal blind testing, or external proficiency testing samples. 4. The lead testing person confirmed the survey findings during an interview on 07/23/26 at 1:15 p.m.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the manufacturer's control package insert, and staff interviews, on the survey date, the laboratory failed to label three of three control vials with the corrected expiration after opening. The findings include: 1. Laboratory observation on 07/23/26 at 8:55 a.m. revealed the Medonic M instrument used to perform CBC w/Diff patient testing. Three levels of Boule Con-diff control lots were observed (22603-01-Low, 22603-02-Normal, 22603-03-High), with 07/07 /26 written on the vials. During the observation, the lead testing person stated that it was the date the controls were opened. The controls were not labeled with a corrected expiration date. 2. A review of the manufacturer's control package insert revealed that the controls were good for 14 days after opening. 3. The lead testing person confirmed the survey findings during an interview on 07/23/26 at 1:15 p.m.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the manufacturer's control package insert, the instrument data log, and a staff interview, the laboratory failed to ensure that three of three CBC w/Diff controls were not used beyond their open expiration date. Approximately 17 patients were reported on 07/22/26, during the period when the controls had expired. The findings include: 1. Laboratory observation on 07/23/26 at 8:55 a.m. revealed the Medonic M instrument used to perform CBC w/Diff patient testing. Three levels of Boule Con-diff control lots were observed (22603-01-Low, 22603-02-Normal, 22603-03-High), with 07/07/26 written on the vials. During the observation, the lead testing person stated that it was the date the controls were opened. 2. A review of the manufacturer's control package insert revealed that the controls were good for 14 days after opening. 3. A review of the instrument data log revealed that approximately 17 patient CBCs w/Diff were performed on 07/22/26 during the period when the controls had expired (patient medical record numbers 57992, 50986, 74135, 74134, 47248, 68746, 53467, 62723, 83703, 84600, 57576, 60242, 84458, 84397, 56128, 56128, 67060). 4. The lead testing person confirmed the survey findings during an interview on 07/23/26 at 1:15 p.m.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) (d)(7) Over time, rotate control material testing among all operators who perform the

	test. This STANDARD is not met as evidenced by: Based on a review of the FORM CMS-209, a review of the laboratory's maintenance logs and quality control records, patient CBC w/Diff results, and staff interview, the laboratory failed to ensure quality control was performed by testing persons three and four (two of four testing personnel) in 2024, 2025, and 2026. 1. A review of the FORM CMS-209 revealed four testing personnel listed who performed patient testing for CBC w/Diff. 2. A review of the laboratory's maintenance and quality control records from November 2024 to the date of the survey on 07/23/26 revealed that testing persons (TP) three and four did not perform CBC w/Diff quality control. 3. A review of randomly selected patient records revealed patient CBC w/Diff testing performed by testing person three (patient number 75765 on 03/02/26; patient numbers 74545 and 81835 on 05/27/26) and by testing person four (patient number 83747 on 05/27/26). 4. The lead testing person confirmed the survey findings during an interview on 07/23/26 at 1:15 p.m.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records, testing personnel records, patient test records, and a staff interview, the laboratory director failed to ensure that two of four testing personnel (testing personnel three and four) participated in proficiency testing in 2025 and 2026. Refer to D2007.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory's testing personnel policy, a review of testing personnel competency records, and staff interview, the laboratory director failed to ensure that policy and procedures for training and competency assessment were established and followed according to the requirements in Subpart M (Refer to D5209).
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii)

	(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii)(E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory; (b)(6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of training documentation and staff interview, training documentation for testing persons three and four did not include instrument or sample troubleshooting, training on controls procedures, training on factors that affect patient test results, review of background counts, or evaluation of quality control data (two of two new testing personnel). The findings include: 1. A review of the training documentation for testing persons three and four revealed the training did not include instrument or sample troubleshooting, training on control procedures, factors that affect patient test results, review of background counts, or evaluation of quality control data. 2. The lead testing person confirmed the survey findings during an interview on 07/23/26 at 1:15 p.m.