Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1046970	02/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Main Street Family Medicine Inc	1306 Highway 45 North, Henderson, 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: CITATION ONE: Based on laboratory observation, a review of the laboratory procedure manual, competency assessment documentation, lack of documentation, and staff interview, the laboratory failed to follow the established policy for competency assessment for three of three testing personnel (TP) who performed wet prep testing in 2024 and 2025. The findings include: 1. Laboratory observation on 02 /24/26 at 8:30 a.m. revealed a microscope used for performing urine microscopic and wet prep examination, and a Sysmex XN 330 used for performing Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) instrument. 2. A review of the laboratory's testing personnel competency assessment policy revealed that "The following six competency procedures are the minimum regulatory requirements for making sure personnel are performing non-waived testing correctly:" The policy listed the six elements required in Subpart M of the Clinical Laboratory Improvement Amendments (CLIA) regulations. 3. A review of the 2024 and 2025 wet prep competency assessment documentation for TP1, TP2, and TP3 revealed that the documentation did not include direct observation of patient testing, review of patient test records, documentation of evaluation of blind testing, or documentation of evaluation of problem-solving skills. 4. The lead testing person confirmed the survey findings during an interview on 02/24/26 at approximately 3:00 p.m. CITATION TWO: Based on laboratory observation, a review of patient test records, lack of documentation, a review of the laboratory's procedure manual, and staff interview, the laboratory policy for competency assessment was not in compliance with Subpart M of the CLIA regulations when the policy did not require reassessment of competency

	when test methods changed, resulting in seven of seven established testing personnel that did not have reassessment of competency when the laboratory implemented a new CBC w/Diff instrument. The findings include: 1. Laboratory observation on 02/24/26 at 8:30 a.m. revealed the Sysmex XN 330 used for patient testing for CBC w/Diff (new since the last survey date). 2. A review of patient test records revealed that patient testing began on 07/24/23 with patient 26803. 3. The laboratory failed to provide documentation of reassessment of competency for seven of seven established testing personnel for the use of the new Sysmex XN 330 CBC w/Diff methodology. 4. A review of the laboratory's testing personnel competency assessment policy revealed no requirement that reassessment of competency was required when a test methodology changed. 5. The laboratory lead confirmed the survey findings during an interview on 02/24/26 at approximately 3:00 p.m.
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. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's operator's manual, the laboratory procedure manual, the laboratory's reagent change records, the laboratory's quality control (QC) records, patient Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) records and staff interview, the laboratory's QC procedure for the Sysmex XN 330 CBC w/Diff instrument was not consistent with the manufacturer's requirements, resulting in the laboratory performing patient testing (nine patients) after a reagent change that occurred on 10/28/25 without first performing QC. The findings include: 1. A review of the manufacturer's operator's manual for the Sysmex XN 330 titled "Basic Operation" revealed the following under section "3.2.2 When QC analysis is performed. QC is performed at the following times. Before sample analysis, After replacement/replenishment of reagent, After instrument maintenance, When there is a concern about the accuracy of analysis values." 2. A review of the laboratory's procedure for the Sysmex XN 330 CBC w/Diff instrument revealed that the laboratory's QC policy was not consistent with manufacturer requirements when it did not require that QC was performed after replacement of reagents, after instrument maintenance, or when there was a concern about patient results. 3. A review of the laboratory's reagent change records revealed that a change in the Cellpack DCL that occurred on 10/24/25 at 10:48 a.m. 4. A review of the laboratory's QC records revealed that QC was not performed after the Cellpack DCL was changed. 5. A review of patient test records revealed that nine patients were reported after the reagent change without QC being performed (Patient numbers 26677, 40455, 31608, 42710, 30468, 37717, 43209, 43776, 26270). 6. The lead testing person confirmed the survey findings during an interview on 02/24/26 at approximately 3:00 p.m.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: CITATION ONE: Based on a review of the laboratory procedure manual, a review of patient test records, lack of documentation, and staff interview, the laboratory failed to perform corrective action for the failure to identify the testing person for three of nine patient test records selected from 2024, 2025, and 2026. The findings include: 1. A review of the laboratory policy for patient test management revealed that "A check will be made to see that appropriate patient/specimen information has been recorded. A verification that all reports are complete with patient's name, date, patient results, units indicated and date and initial of performing tech have been recorded on our logs and patient reports." 2. A review of CBC w/Diff, wet prep and urine microscopy patient records revealed that the identity of the person who performed the testing could not be identified for three of nine random patients pulled for review (patient number four - urine microscopy performed on 04/01/24, patient number eight - wet prep performed on 08/16/25, and patient number nine - wet prep performed on 02/11 /26. 3. The laboratory failed to provide documentation of corrective action for the missing testing personnel identity for the three patients identified by the surveyor from 2024, 2025, and 2026. 4. The lead testing person confirmed the survey findings during an interview on 02/24/26 at approximately 3 p.m. CITATION TWO: Based on a review of patient test results, quality assessment documentation, and staff interview, the laboratory failed to have a process in place for review of background counts for the Sysmex XN 330 Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) instrument in 2024, 2025 and 2026. The findings include: 1. A review of patient test results for CBC w/Diff revealed patient testing for CBC w /Diff reported on 03/28/24 for patient number 33131, on 06/18/25 for patient 36694, and on 02/23/26 for patient 24418. 2. A review of the quality assessment records for the Sysmex XN 330 revealed that the background counts for March 2024 and June 2025 had not been reviewed to determine if they had been performed or if they were acceptable. 3. The lead testing person confirmed that the laboratory failed to have a process in place for review of the background counts for the Sysmex XN 330 CBC w /Diff instrument during an interview on 02/24/26 at approximately 3:00 p.m. She stated that the background counts were not printed for review, and there was no process in place for online review of the records in the Sysmex Beyond Care System.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the instrument validation records, a review of patient test records, and staff interview, the laboratory director failed to review validation records for the Sysmex XN 330 instrument, with patient testing beginning on 07/24/23 with patient 26703. The findings include: 1. Laboratory observation on 02/24/26 at 8:30 a.m. revealed the Sysmex XN 330 used for patient

	testing for CBC w/Diff (new since the last survey date). 2. A review of validation records for the Sysmex XN 330 revealed that the initial calibration, carryover study, and reportable range verification had not been reviewed by the laboratory director. 3. A review of patient test reports revealed that patient testing on the new Sysmex XN 330 instrument began on 07/24/23 with patient identification number 26703. 4. The laboratory lead confirmed the survey findings during an interview on 02/24/26 at 9:30 a.m.