Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2176977	06/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mainline Health Systems Inc	1012 E Church St, Warren, AR	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Through a review of proficiency testing records, lack of documentation, and interviews with staff, it was determined the laboratory testing personnel and director failed to sign the attestation statements for two of two proficiency testing events. Survey findings follow: A. A review of the proficiency testing documentation revealed for the second testing event of 2020 and the first testing event of 2021 the attestation statement had no signatures of testing personnel or director. B. In an interview on 6/8/2021 at 10:20, laboratory employee #3 (as listed on CMS form 209) confirmed that the forms lacked the required signatures.
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 review of personnel records, lack of documentation and interviews, it was determined that the competency of the technical consultant was not assessed by the laboratory director. Survey Findings Follow: A. A review of personnel records for three of three laboratory personnel revealed that there was no documentation of the

	annual competency evaluation for the technical consultant in 2020 or 2021. B. Upon request the laboratory could not provide documentation of annual competency for the technical consultant for 2020 and 2021. C. In an interview on 06/14/2021 at 10:00, laboratory personnel #3 confirmed that there was no assessment of competency by laboratory director for the technical consultant.
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: . Through a review of the laboratory procedure manual, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to approve, sign, and date the laboratory procedures. Survey findings include: A. During a review of the laboratory procedures it was determined the procedure manual and individual procedures lacked the directors approval signature and date of approval. B. In an interview at 10:20 on 6/14/21, laboratory employee #3 (as listed on the form CMS-209) confirmed the laboratory directors written approval of the laboratory procedures was not available.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Through a review of the manufacturer's instruction for Sysmex XP-300 Hematology Analyzer, patient results, lack of documentation and interview with laboratory personnel, it was determined the laboratory failed to follow manufacturer's instructions for resolving flags prior to their release to the healthcare provider. As evidenced by: A. A review of manufacturer's instruction for the Sysmex XP-300 Hematology analyzer page 8-21 and 8-22 "Flagging Summary" revealed the manufacturer identified the following flags and possible actions for: Platelet Flags: Flag [AG]: Probable cause: Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin. Correction: Check smear. B. A review of patient Complete Blood Count (CBC) results revealed twenty of twenty patients result had Platelet flags that were not resolved prior to their release to the healthcare provider. Patient # 00001 Flag: AG (PLT Count 251) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00002 Flag: AG (PLT Count 243) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00003 Flag: AG (PLT Count 102) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00004 Flag: AG (PLT Count 247) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00005 Flag: AG (PLT Count 400) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00006 Flag: AG (PLT Count 391) No repeat analysis

	performed specimen was not sent to reference laboratory. Patient #00007 Flag: AG (PLT Count 444) No repeat analysis performed specimen was not sent to reference laboratory. Patient #00008 Flag: AG (PLT Count 340) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00009 Flag: AG (PLT Count 391) No repeat analysis performed specimen was not sent to reference laboratory. Patient #00010 Flag: AG (PLT Count 309) No repeat analysis performed specimen was not sent to reference laboratory. Patient #00011 Flag: AG (PLT Count 354) No repeat analysis performed specimen was not sent to reference laboratory. Patient #00012 Flag: AG (PLT Count 89) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00013 Flag: AG (PLT Count 302) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00014 Flag: AG (PLT Count 354) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00015 Flag: AG (PLT Count 403) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00016 Flag: AG (PLT Count 501) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00017 Flag: AG (PLT Count 64) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00018 Flag: AG (PLT Count 240) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00019 Flag: AG (PLT Count 131) No repeat analysis performed specimen was not sent to reference laboratory. Patient # 00020 Flag: AG (PLT Count 343) No repeat analysis performed specimen was not sent to reference laboratory. D. The Surveyor requested documentation of smear review prior to release of results to healthcare provider. No documentation was provided. E. In an interview on 6/8/21 at 1300, technical consultant confirmed the findings and the specimens were not sent to the reference laboratory for confirmation.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: . Through observations made during a tour of the laboratory and interviews with staff, it was determined the laboratory had supplies available for use when they had exceeded their expiration date. Survey findings follow: A. During a tour of the laboratory on 6/8/2021 at 10:30 a.m., the surveyor observed 2 boxes of Aeromed COVID-19 test kits Lot #201117006 expiration date 4/30/2021. B. In an interview on 6/08/21 at 10:30 a.m. laboratory employee #1 (as listed on CMS 209) confirmed the supplies were available for use when they had exceeded their expiration date.
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: . Through a review of personnel records for two of two testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to specify, in writing, the procedures each individual is authorized to perform, and whether supervision is required for reporting patient test results. Survey findings include: A. During a review of personnel records for two of two testing personnel, it was determined that testing personnel #1 and #2 (as listed on form CMS-209) had no written authorization to perform testing without direct supervision. B. During an interview, at 10:30 a.m. on 6/08/2021, laboratory employee #3 (as listed on the form CMS-209) confirmed that written authorizations to test were not available.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Through review of the CMS form 209, personnel records, lack of documentation, and interview with staff, it was determined that the technical consultant failed to document personnel competency on an annual basis for two of two testing personnel identified on the CMS form 209. Survey findings follow: A. A review of personnel records for testing personnel revealed that the technical consultant failed to evaluate the competency for testing personnel #1 and #2 (as listed on form CMS 209) for 2020 and 2021. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 6/8/2021 at 10:30 a.m., the technical consultant confirmed that competency evaluations had not been performed on testing personnel #1 and #2 (as listed on form CMS 209).