Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2229845	11/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Usa Health Freestanding Emergency Department	181 Hillcrest Road, Mobile, AL	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on interviews with the General Supervisor and a review of the Procedure Manual, the laboratory failed to have a written procedure for Cerebrospinal Fluid (CSF) Cell Count testing. This was noted from the date patient testing started (3/14 /2022) to the date of the current survey (11/30/2022). The findings include: 1. During an interview on 11/30/2022 at 11:15 AM, the General Supervisor explained the Sysmex XN-2000 Hematology analyzer has the capability of analyzing CSF as well as whole blood specimens for cell counts. 2. A review of the Procedure Manual revealed a procedure for the Sysmex XN-2000 instrument, however, whole blood was listed as the only acceptable specimen type. Furthermore, there were no instructions included detailing how to analyze body fluids. 3. During an interview on 11/30/2022 at 11:15 AM, the General Supervisor confirmed the absence of a procedure detailing CSF cell counts on the Sysmex XN-2000.
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:

	Based on a review of patient logs, a review of the Procedure Manual, and an interview with the Point of Care Coordinator, the Laboratory Director failed to approve the Procedure Manual prior to patient testing. The findings include: 1. A review of patient logs revealed the laboratory began patient testing on March 14, 2022. 2. A review of the Procedure Manual revealed an approval from the Laboratory Director dated 6/3 /2022. 3. During an interview on 11/29/2022 at 10:30 AM, the Point of Care Coordinator confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the validation study for the Sysmex XN 2000 Hematology analyzer, interviews with the General Supervisor, and a review of patient logs, the laboratory failed to verify performance specifications for Cerebrospinal Fluid (CSF) samples prior to reporting patient test results. The surveyor noted one patient was performed from 3/14/22 to 11/30/2022, the date of the current survey. The findings include: 1. A review of the validation study for the Sysmex XN 2000 Hematology analyzer revealed two side by side analyzers (Right: SN 81022; Left: SN 81029) were validated to run whole blood samples for Complete Blood Counts (CBC). SN 81029 validation included a method comparison for CSF samples. 2. During an interview on 11/30/2022 at 11:15 AM, the General Supervisor explained both the left and right analyzers were set up to run CSF samples. 3. A review of patient logs revealed a patient had a CSF cell count performed on 7/13/2022 on SN 81022. 4. During an interview on 11/30/2022 at 4:00 PM, the General Supervisor confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of a final test report and an interview with the Laboratory Manager, the laboratory failed to include the name and address of the laboratory where the test was performed on the test report. This was noted from the date patient testing started

	(3/14/2022) to the current survey (11/30/2022). The findings include: 1. A review of a patient's cumulative final test report revealed "FED" under the "Location" field, indicating the location to be "Freestanding Emergency Department". No other identifying information for this location was included on the report. 2. During an interview on 11/30/2022 at 4:00 PM, the Laboratory Manager confirmed the above finding.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on a review of personnel evaluation records and an interview with the General Supervisor, the Technical Consultant failed to ensure testing personnel had documentation of training before performing patient tests. This was noted for eight out of eight Testing Personnel listed on the Form CMS-209 (Laboratory Personnel Report) from the date patient testing started (3/14/2022) to the date of the current survey (10/5/2022). The findings include: 1. A review of personnel evaluation records revealed the following: a) Initial training for the Sysmex XN-2000 Hematology analyzer, Urine Microscopic Exams, Serum Pregnancy, and Serum Infectious Mononucleosis (Mono) was not performed and documented for Testing Personnel #1, #2, #3, #4, #5, #6, #7, and #8. b) Initial training for the Sysmex CA-660 Coagulation analyzer was not performed and documented for Testing Personnel #6 and Testing Personnel #8 2. During an interview on 11/29/2022 at 2:30 PM, the General Supervisor confirmed the above findings.
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: Based on a review of Testing Personnel records and an interview with the Technical Consultant, the Technical Consultant failed to implement and document evaluations that included the six minimal regulatory requirements for assessment of competency of Urine Microscopic Exams and Serum Infectious Mononucleosis (Mono). This was noted for three out of three Testing Personnel who have had a six month evaluation completed from 3/14/2022 to the date of the current survey (11/30/2022). The findings include: 1. A review of Testing Personnel records revealed the following: a) Competency assessments did not include the six minimal regulatory requirements for assessment of competency as specified by CLIA. The aforementioned document included a column titled "Assessment Categories" with numbers 1 - 6 correlating to each regulatory requirement for each testing system. b) Urine Microscopic Exam failed to assess category #4, a direct observation of instrument maintenance/function checks. c) Serum Mono was not included as a testing system on this document. 2.

	During an interview at 2:30 PM on 11/29/2022, the Technical Consultant confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel evaluation records and an interview with the General Supervisor, the Technical Consultant failed to evaluate and document the performance of individuals responsible for moderate complex testing at least semi annually during the first year of patient testing. This was noted for one out of eight Testing Personnel from the date patient testing started (3/14/2022) to the date of the current survey (11 /30/2022). The findings include: 1. A review of personnel records revealed the Technical Consultant failed to perform and document the semi-annual competency evaluation (due July 2022) for all moderate complexity testing for Testing Personnel #8. 2. During an interview on 11/29/2022 at 2:30 PM, the General Supervisor confirmed the above findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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: Based on a review of personnel evaluation records and an interview with the Technical Supervisor, the Technical Supervisor failed to ensure testing personnel had documentation of training before performing patient tests. This was noted for eight out of eight Testing Personnel listed on the Form CMS-209 (Laboratory Personnel Report) from the date patient testing started (3/14/2022) to the date of the current survey (11/30/2022). The findings include: 1. A review of personnel evaluation records revealed initial training for Manual Complete Blood Counts (CBC), Manual Cerebrospinal Fluid (CSF) Cell Counts, and Gram Stains was not performed and documented for Testing Personnel #1, #2, #3, #4, #5, #6, #7, and #8. 2. During an interview on 11/29/2022 at 2:30 PM, the Technical Supervisor confirmed the above findings.