Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0339756	02/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Western Reserve Hospital	1900 23rd Street, Cuyahoga Falls, OH	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and an interview with the Administrative Director (AD), the laboratory failed to test gram stain proficiency testing (PT) samples in the same manner as patients' specimens for all three testing events in 2020 and 2021. Findings Include: 1. The laboratory failed to test 15 out of 15 of the gram stain and morphology proficiency testing (PT) samples the same number of times as they routinely tested patient specimens in 2020 and 2021. (Refer to D2010)
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on record review and an interview with the Administrative Director (AD), the laboratory failed to test 15 out of 15 of the gram stain and morphology proficiency

	testing (PT) samples the same number of times as they routinely tested patient specimens in 2020 and 2021. Findings Include: 1. Review of the laboratory's "Proficiency Testing" policy and procedure, approved, signed, and dated by the Laboratory Director on 11/24/2020, found the following instructions: "c. Laboratory personnel are prohibited from repeat testing of PT samples..." 2. Review of six out of six of the laboratory's 2020 and 2021 American Proficiency Institute (API) gram stain and morphology PT events, provided on the date of the inspection, revealed the laboratory tested all gram stain and morphology PT samples more times than it routinely tested patient samples prior to the submission due date assigned by the PT provider for 30 out of 30 testing samples. 1st testing event 2020 GS-01, GS-02, GS-03, GS-04, GS-05 tested by 4 TP prior to result submission 2nd testing event 2020 GS-06, GS-07, GS-08, GS-09, GS-10 tested by 4 TP prior to result submission 3rd testing event 2020 GS-11, GS-12, GS-13, GS-14, GS-15 tested by 6 TP prior to result submission 1st testing event 2021 GS-01, GS-02, GS-03, GS-04, GS-05 tested by 11 TP prior to result submission 2nd testing event 2021 GS-06, GS-07, GS-08, GS-09, GS-10 tested by 9 TP prior to result submission 3rd testing event 2021 GS-11, GS-12, GS-13, GS-14, GS-15 tested by 6 TP prior to result submission 3. The AD confirmed the laboratory tested the above mentioned 2020 and 2021 PT samples more times than it routinely tested patient samples prior to the result submission due date set by API. The interview occurred on 02/07/2022 at 2;15 PM.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and an interview with the Administrative Director (AD), the laboratory failed to achieve a proficiency testing (PT) score of 80% for the analytes potassium (K) and sodium (Na) in the second PT event in 2020 and procalcitonin in the first PT event in 2020 in the specialty of Chemistry. Patient K, Na and procalcitonin testing had the potential to be affected by this deficient practice during the respective testing events in 2020. Findings Include: 1. Review of the laboratory's 2020 American Proficiency Institute (API) Chemistry PT documentation, provided on the date of the inspection, revealed the following unsatisfactory analyte testing scores: First PT Event 2020 Procalcitonin; 67% Second PT Event 2020 K; 67% Na; 67% %; percent 2. The AD confirmed the unsatisfactory PT scores for the analytes indicated above. The interview occurred on 02/07/2022 2:15 P.M.
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 record review and an interview with the Administrative Director (AD), the laboratory failed to follow their "Proficiency Testing" (PT) policy and procedure for

	the number of times testing gram stain and morphology PT samples. All gram stain testing procedures performed in this laboratory had the potential to be affected by this deficient practice. Findings Include: 1. Review of the "Proficiency Testing" policy and procedure, approved via signature and date by the Laboratory Director on 01/12/2022 and provided on the date of the inspection, found the following statements: "Laboratory personnel are prohibited from repeat testing of PT samples..." "Testing personnel will handle survey materials as if they were patient samples with no special treatment, duplicate analyses, etc., unless it is standard for a particular test." "Testing personnel will perform analysis according to those instructions and established laboratory procedures for testing that analyte, integrating testing into the routine laboratory workload using the same primary method systems as for patient/client samples." 2. Review of six out of six of the laboratory's 2020 and 2021 American Proficiency Institute (API) gram stain and morphology PT events, provided on the date of the inspection, revealed the laboratory tested all gram stain and morphology PT samples more times than it routinely tested patient samples prior to the submission due date assigned by the PT provider for 30 out of 30 testing samples. 1st testing event 2020 GS-01, GS-02, GS-03, GS-04, GS-05 tested by 4 TP prior to result submission 2nd testing event 2020 GS-06, GS-07, GS-08, GS-09, GS-10 tested by 4 TP prior to result submission 3rd testing event 2020 GS-11, GS-12, GS-13, GS-14, GS-15 tested by 6 TP prior to result submission 1st testing event 2021 GS-01, GS-02, GS-03, GS-04, GS-05 tested by 11 TP prior to result submission 2nd testing event 2021 GS-06, GS-07, GS-08, GS-09, GS-10 tested by 9 TP prior to result submission 3rd testing event 2021 GS-11, GS-12, GS-13, GS-14, GS-15 tested by 6 TP prior to result submission 3. The AD confirmed the laboratory tested the above mentioned 2020 and 2021 PT samples more times than it routinely tested patient samples prior to the result submission due date set by API and did not follow their PT policy and procedure. The interview occurred on 02/07/2022 at 2;15 PM.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review and an interview with the Administrative Director (AD), the Technical Supervisor (TS) failed to evaluate and document the competency of four out of 44 testing personnel (TP) who were responsible for moderate and high complexity testing procedures at least annually after the first year. All patient testing performed by TP3, TP4, TP5 and TP7 in the specialties of microbiology, chemistry, immunohematology and hematology in 2020 and 2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Competency Assessment Program" policy and procedure, approved, signed and dated by the Laboratory Director on 04/01/2017, and provided on the date of the inspection, revealed the following: "Procedure 1. Delegation of competency...review Testing Personnel Review Level Senior Techs/ Laboratory Director Coordinators (high complexity) Technologists/ Senior Techs, Technicians Coordinator or designated testing personnel" 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 02/04/202, revealed 44 individuals

	listed as TP who had tested patient specimens and were responsible for moderate and high complexity testing procedures. 3. Review of the laboratory's 2020 and 2021 competency assessment documentation, provided on the date of the inspection, revealed the competencies of TP3, TP4, TP5 and TP7 were assessed by the following TP that were not designated as a TS: TP3; microbiology by TP18: 08/2020, 07/2021 TP4; chemistry by TP13; 11/2020, 07/2021 immunohematology by TP13; 10/2020, 09 /2021 TP5; chemistry by TP15; 10/2020, 06/2021 TP7; hematology by TP15; 09/2021 4. The Inspector requested the laboratory's 2020 and 2021 competency assessment documentation for TP3, TP4, TP5 and TP7 that was assessed by a TS from the AD. The AD confirmed TP3, TP4, TP5 and TP7 did not have their competency assessments completed and documented by a TS in 2020 and 2021, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/07/2022 10:16 AM.