Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0330837	(X3) Date Survey Completed 12/20/2023
Name of Provider or Supplier Wyandot Memorial Hospital	**Street Address, City, State** 885 North Sandusky Avenue, Upper Sandusky, 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
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: Item I: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to establish and follow written policies and procedures to assess the competency of the GS based on the responsibilities of the role, at a frequency determined by the laboratory. This deficient practice had the potential to affect 473,130 out of 473,130 patient tests performed between 12/01/2022 through 12/20/2023 in the specialities of Microbiology, Diagnostic Immunology, Chemistry and Hematology. Findings Include: 1. Review of the laboratory's policy and procedure manual, provided on the date of the inspection, failed to find competency assessment procedures for the GS based on the responsibilities of the role, at a frequency determined by the laboratory. 2. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 12/20/2023, found one individual listed and qualified by the Laboratory Director to function as a GS. 3. Review of the laboratory's competency assessment documentation failed to find a competency assessment for the GS based on the responsibilities of the role, at a frequency determined by the laboratory. 4. The Surveyor requested the laboratory's policy and procedure from the GS for the competency assessment for the GS and the competency assessment documentation for the GS based on the responsibilities of the role. The GS confirmed the laboratory did not establish a policy and procedure for the assessment of the GS based on the responsibilities of the position, at a frequency determined by the laboratory, the laboratory did not assess the competency of the GS and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/20/2023 at 3:40 PM. Item II: Based on record review and an interview

	with the General Supervisor (GS), the laboratory failed to follow a written policy and procedure to assess competency of Testing Personnel (TP) #1 and TP #4 in the year 2022, as specified in the personnel requirements in subpart M. This deficient practice had the potential to affect 473,130 out of 473,130 patient tests performed between 12 /01/2022 through 12/20/2023 in the specialities of Microbiology, Diagnostic Immunology, Chemistry and Hematology. Findings Include: 1. A review of the laboratory's CMS-209 form, approved and signed by the Lab Director on 12/20/2023, found nine individuals listed as TP. 2. A review of the laboratory's "Competency Assessment" policy and procedure found the following statement: "...employees must demonstrate appropriate training checklists, and then competency at six months of service and annually thereafter..." 3. A review of the laboratory's competency assessment data failed to find competency assessments for TP #1 and TP #4 in the years 2022 and 2023. 4. The surveyor requested competency assessment documentation from the GS for the year 2022 and 2023 for TP #1 and TP #4. 5. The GS confirmed that the laboratory failed to perform a competency assessment for TP #1 and TP #4 in the years 2022 and 2023. The interviews occurred on 12/20/23 at 3: 37 PM and 3:43 PM respectively.
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interviews with the General Supervisor (GS) and Testing Personnel (TP) #8, the laboratory failed to perform, document and follow quality control (QC) procedures for the hematology manual differential testing performed to detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. This deficient practice had the potential to affect 237 out of 237 patients tested from 12/01/2022 through 12/20/2023 in the speciality of Hematology. Findings Include: 1. Review of the laboratory's policies and procedures failed to find instructions for performing and documenting QC for hematology manual differential testing. 2. Review of the laboratory's hematology documentation failed to find evidence that QC was performed and documented for hematology manual differential testing. 3. An interview with TP #8 revealed that the laboratory did not perform and document QC for hematology manual differential testing. The interview occurred on 12/20/2023 at 3:07 PM. 4. The GS confirmed that the laboratory failed to perform and document QC for hematology manual differential testing. The interview occurred on 12/20/2023 at 3:45 PM.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Item I: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to perform and document quality control (QC) procedures for the qualitative microscopic urinalysis each day of testing. This deficient practice had the potential to affect 2,045 out of 2,045 patients tested from 12/01/2022 through 12/20/2023 in the subspecialty of Urinalysis. Findings Include: 1. Review of the laboratory's policies and procedures failed to find instructions for performing and documenting QC for microscopic urinalysis testing. 2. Review of the laboratory's Urinalysis documentation failed to find evidence that QC was performed and documented for microscopic urinalysis testing. 3. The surveyor requested the QC records from the GS for the microscopic urinalysis test. 4. The GS confirmed that the laboratory failed to perform and document QC for the microscopic urinalysis test. The interview occurred on 12/20/2023 at 3:45 PM. Item II: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to perform and document quality control (QC) procedures for the qualitative microscopic vaginal wet preparation (wet prep) each day of testing. This deficient practice had the potential to affect 305 out of 305 patients tested from 12/01/2022 through 12/20/2023 in the subspecialties of Mycology and Parasitology. Findings Include: 1. Review of the laboratory's policies and procedures failed to find instructions for performing and documenting QC for the microscopic vaginal wet prep test. 2. Review of the laboratory's Mycology and Parasitology documentation failed to find evidence that QC was performed and documented for the microscopic vaginal wet prep test. 3. The surveyor requested the QC records from the GS for the microscopic vaginal wet prep test. 4. The GS confirmed that the laboratory failed to perform and document QC for the microscopic vaginal wet prep test. The interview occurred on 12/20/2023 at 3:45 PM. Item III: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to perform and document quality control (QC) procedures for the qualitative microscopic post vasectomy for the presence and absence of sperm each day of testing. This deficient practice had the potential to affect 34 out of 34 patients tested from 12/01/2022 through 12/20/2023 in the speciality of Hematology. Findings Include: 1. Review of the laboratory's policies and procedures failed to find instructions for performing and documenting QC for the microscopic post vasectomy for the presence and absence of sperm test. 2. Review of the laboratory's Hematology documentation failed to find evidence that QC was performed and documented for the microscopic post vasectomy for the presence and absence of sperm test. 3. The surveyor requested the QC records from the GS for the microscopic post vasectomy for the presence and absence of sperm test. 4. The GS confirmed that the laboratory failed to perform and document QC for the microscopic vaginal wet prep test. The interview occurred on 12/20/2023 at 3:45 PM. Item IV: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to perform and document quality control (QC) procedures for the qualitative microscopic body fluid crystal test each day of testing. This deficient practice had the potential to affect eight out of eight patients tested from 12/01/2022 through 12/20/2023 in the speciality of Hematology. Findings Include: 1. Review of the laboratory's policies and procedures failed to find instructions for performing and documenting QC for the microscopic body fluid crystal test. 2. Review of the laboratory's Hematology documentation failed

	to find evidence that QC was performed and documented for the microscopic body fluid crystal test. 3. The surveyor requested the QC records from the GS for the microscopic body fluid crystal test. 4. The GS confirmed that the laboratory failed to perform and document QC for the microscopic body fluid crystal test. The interview occurred on 12/20/2023 at 3:45 PM. Item V: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to perform and document quality control (QC) procedures for the qualitative microscopic pinworm prep test each day of testing. This deficient practice had the potential to affect two out of two patients tested from 12/01/2022 through 12/20/2023 in the subspecialty of Parasitology. Findings Include: 1. Review of the laboratory's policies and procedures failed to find instructions for performing and documenting QC for the microscopic pinworm prep test. 2. Review of the laboratory's Parasitology documentation failed to find evidence that QC was performed and documented for the microscopic pinworm prep test. 3. The surveyor requested the QC records for the microscopic pinworm prep test. 4. The GS confirmed that the laboratory failed to perform and document QC for the microscopic pinworm prep test. The interview occurred on 12/20/2023 at 3:45 PM.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to provide education documents to ensure that the GS met the minimum qualification requirements of 493.1461 to provide general supervision in accordance with 493.1463 in the specialities of Diagnostic Immunology, Microbiology, Chemistry and Hematology. Findings Include: 1. The laboratory failed to provide education documents to ensure the GS met the minimum qualification requirements of 493.1461 in the specialties of Diagnostic Immunology, Microbiology, Chemistry and Hematology. (Refer to D6143)
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a

general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on record review and an interview with General Supervisor (GS), the laboratory failed to provide education documents to ensure one out of one GS met the minimum qualification requirements under 493.1461 for high complexity testing. This deficient practice had the potential to affect 473,130 out of 473,130 patient tests performed between 12/01/2022 through 12/20/2023 in the specialities of Microbiology, Diagnostic Immunology, Chemistry and Hematology. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 01/31/2023 found one individual listed and certified by the Laboratory Director to fulfill the position and responsibilities of a GS for the high complexity Immunology, Microbiology, Chemistry and Hematology testing procedures performed. 2. The Surveyor requested education documents from the GS for the GS listed on the Form CMS-209. 3. The GS confirmed that the laboratory did not have the education documentation to support the GS met the minimum qualification requirements for high complexity testing and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01

	/30/2023 at 11:10 AM.