Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656594	05/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Osdh Public Health Laboratory	4615 West Lake View Rd, Stillwater, OK	

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
D0000	Federal surveyors from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA recertification survey at the Oklahoma State Department of Health Publich Health Laboratory from May 13, 2025, to May 15, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. The following standard-level deficiencies were found during the CLIA recertification survey that concluded on May 15, 2025, at 11:15 am.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of a sampling of proficiency records (PT) records, a lack of 2023 PT records, and interview with technical supervisor (TS) #5, the laboratory failed to retain two of two years of PT records from 2023 to 2024. Finding Included: 1. A review of microbiology PT records from May 13, 2025 at 2:00 pm revealed, the following PT attestation could not be provided: a. College of American Pathologist (CAP) - Nucleic Acid Amplification, Respiratory Limited (ID3) - B - 2024. b. CAP - ID3 - C - 2024. c. U.S. Centers for Disease Control and Prevention (CDC) - Enteric Disease Laboratory Branch (EDLB) - QA Panel. 2. The laboratory could not provide the following microbiology and molecular testing PT records by the end of the survey on May 15, 2025 at 2:00 pm: a. Wisconsin State Laboratory of Hygiene (WSLH) - Carbapenem-resistant Enterobacteriaceae (CRE) identification (ID) and Polymerase Chain Reaction (PCR) - 2023 events. b. CDC - EDLB - 2023 events. 3. By interview with TS#5 on May 15, 2025 at 1:00 pm confirmed, PT records were not retained for two years and were not available at the time of survey.

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 the laboratory quality standard operating procedures (SOP), review of laboratory personnel records, and interview with technical supervisor #5, the laboratory failed to establish a competency assessment procedure to assess the competency of 17 out of 19 supervisory personnel for their supervisory responsibilities from August 2023 to May 2025. Finding Included: 1. The laboratory personnel report (Form CMS-209) signed by the laboratory director on May 6, 2025 listed the following nineteen supervisory personnel: a. Two clinical consultants (CC). b. Six technical supervisors (TS). c. Seven technical consultants (TC). d. Four general supervisors (GS). 2. On May 12, 2025 at 10:45 am, review of laboratory personal competency assessment records revealed, 17 out of 19 supervisory personnel were not assessed for competency in 2023 or 2024. 3. Review of the laboratory quality assessment SOP's, competency assessment section on May 12, 2025 at 11:00 am, revealed the laboratory did not establish procedures to assess the competency for supervisory personnel. 4. By interview on May 12, 2025 at 11:30 am with TS #5, confirmed the competency assessment procedures did not include the assessment of competency for supervisory personnel.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: I.Based on review of the laboratory's policy, in direct observation, and interview with Testing person #4 (from the CMS-209), the laboratory failed to follow their own policy in regards to urine Aptima gonorrhea and chlamydia specimens containing precipitate as evidenced by: 1.In review of the laboratory's procedure, Aptima Combo Assay states, "If a urine specimen tube contains precipitate that may interfere with pipetting of the sample on the Panter system, heat the specimen at 37 degrees C for up to 5 minutes." 2. In direct observation at 1229 on 5-13-2025, the laboratory only had one water bath serial #1161975291291211 near the panther system set at 56 degrees C. There were no other water baths to heat up the specimens at 37 degrees. 3.In an interview with Testing Person #4 at 1230 on 5-13-2025 the federal surveyor asked how he heats up their urine patient specimen if there is precipitate seen in the tubes. He stated that if urine specimens (for Aptima) had precipitate in them, they would heat them up in the water bath at 56 degrees C. II. Based on review of the laboratory's policy, laboratory records, and interview with the Laboratory director, the laboratory failed to follow their own policy for quarterly environmental monitoring for the Gastrointestinal Pathogen Panel (GPP) for 7 months (September 2024 to April 2025) reviewed as evidenced by: 1. In review of the the laboratory's policy Luminex X Tag

	GGP policy pg. 12 under Environmental Monitoring states, "Environmental monitoring should be performed quarterly by testing swab samples collected from pre-PCR area surfaces..." 2. In review of the laboratory's records for September 2024 to April 2025, the laboratory failed to perform a environmental monitoring in 4th quarter 2024 (October 2024-January 2025). 3. In an interview with the laboratory director 5-15-2025 at 1140 he confirmed the findings that they did not perform a 4th quarter 2024 environmental testing according to the policy. 47272 III.Based on a written laboratory policy and procedure, record review, and interview with testing person #3 (TP #3) and technical supervisor #3 (TS #3), the laboratory failed to follow its written procedure for IEF (Isoelectric Focusing) hemoglobinopathy testing. Findings include: 1. On 05/15/25, TP #3 confirmed the laboratory performed IEF (Isoelectric Focusing) testing to screen for neonatal and adult hemoglobinopathies. 2. Review of the laboratory's written "Hemoglobinopathy" policy and procedure "QUALITY CONTROL" section "New Lot of Reagents" stated, "Fill out validation form, attach a scan of the gel ...". 3. Record review from 05/01/24 through 11/12/24 of four new lots of reagents (lot# 752252, lot# 752685, lot# 753164, lot# 756131) revealed no evidence of documented validation forms. 4. Interview on 05/15/25 at 10:40 am with TS #3 confirmed the findings above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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: Based on review of manufacturer's package insert, patient test records, and interview with General Supervisor #4 , the laboratory failed to follow the Hologic Aptima gonorrhea and chlamydia (GC/CT) manufacturer's instructions under the limitations section three of three patients review that were under the age of 14 as evidenced by: 1. In review of the manufacturer's instructions states under limitations, "The performance of the AC2 assay has not been evaluated in adolescents less than 14." 2. In review of the patient testing, the following four patients were under the age of 14: a. 25Y0039084 received date: 5/1/2025, testing date: 5/1/2025, date of birth: 6-22-2011, 13 years old. b.25Y0040559 received date: 5/5/2025 testing date: 5/5/2025, date of birth: 12-29-2011, 13 years old. c. 25Y0040217 received date: 5/2/2025 testing date: 5 /2/2025, date of birth : 8-29-2011, 13 years old. 3. In interview with General Supervisor 5-13-2025 at 1421 at 5-13-2025, she confirmed that there were three individuals under the age of 14.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test

reports.

This STANDARD is not met as evidenced by:
I. Based on the review of equipment temperature records, review of laboratory standard operating procedures (SOP) and interview with the laboratory personnel, the laboratory failed to document the temperature for 1 of 1 heating block used for non-variola testing and 1 of 1 bead sterilizer used for mCIM (Modified Carbapenem Inactivation Method) testing from August 2023 to May 2025. Finding Included: 1. The mCIM SOP, prepare trypticase soy broth cultures, 3. states, "with a clear pair of forceps/tweezers (wipe with alcohol pad and then heated to 278 - 282 degrees Celsius with a bead sterilizer for at least 1 min)". 2. The non-variola orthopoxvirus real time PCR SOP, DNA isolation and purification, 2. lysis of samples, g. states, "incubate at 56 degrees Celsius in a heating block for >=15 minutes to overnight". 3. Review of temperature logs revealed the following: a. On May 14, 2024 at 11:40 am - 1 of 1 Fisherbrand Micro Bead Sterilizer - January 1, 2024 to July 10, 2024 - temperatures were not documented. b. On May 15, 2025 at 11:47 am - 1 of 1 Fisher Heat block - August 2023 to May 2025 - temperatures were not documented. 4. By interview with the microbiology laboratory supervisor on May 14, 2025 at 11:50 am, confirmed temperatures were not documented for the mCIM bead sterilizer from January 1, 2024 to July 10, 2024. 5. By interview with the molecular personnel on May 15, 2025 at 12: 00 pm, confirmed temperatures were not documented for the heat block from August 2023 to May 2025. Key: PCR - Polymerase Chain Reaction. DNA - Deoxyribonucleic acid. 47272 II. Based on manufacturers' instructions, record review, and interview with technical supervisor #3 (TS #3), the laboratory failed to follow Resolve Hemoglobin Kit Gel Dryer manufacturers' instructions for 20 of 20 days of patient testing. Findings include: 1. On 05/15/25, TS #3 confirmed the laboratory performed hemoglobin variant testing using the Resolve Hemoglobin Kit. 2. Review of the manufacturers' Gel Dryer instructions stated, "Capable of drying gels at +50C to +70C for approximately 75 minutes". 3. Record review on 05/15/25 revealed Gel Dryer documented temperatures greater than 70C for 20 of 20 days a. 01/02/25 - 75C b. 01 /03/25 - 75C c. 01/06/25 - 76C d. 01/07/25 - 76C e. 01/08/25 - 75C f. 01/09/25 - 76C g. 01/13/25 - 75C h. 01/14/25 - 76C i. 01/15/25 - 75C j. 01/16/25 - 76C k. 01/17/25 - 75C l. 01/21/25 - 76C m. 01/22/25 - 75C n. 01/23/25 - 75C o. 01/24/25 -76C p. 01/27 /25 - 76C q. 01/28/25 - 75C r. 01/29/25 - 74C s. 01/30/25 - 74C t. 01/31/25 - 75C 4. Interview on 05/15/25 at 10:35 am with TS #3 confirmed the findings above. III. Based on observation, manufacturers' instructions, and interview with technical supervisor #3 (TS #3), the laboratory failed to ensure 96-well spectral calibration plates were stored according to manufacturers' instructions for 7 of 8 days. Findings include: 1. On 05/15/25, TS #3 confirmed the Applied Biosystems Fast 96-Well Spectral Calibration Plates with NEO Dye, Applied Biosystems Fast 96-Well Spectral Calibration Plates WSYBR with Green Dye, and Applied Biosystems Fast 96-Well Spectral Calibration Plates with ROX Dye was used for Newborn Screening testing. 2. Observation on 05/15/25 at 09:25 am of the contents in the Thermo Fisher Freezer (serial # 20170015) revealed the following: a. Three boxes (lot#2411227) of Applied Biosystems Fast 96-Well Spectral Calibration Plates with NEO Dye with a manufacturers' storage requirement of -15C to -25C b. One box (lot#2411226) of Applied Biosystems Fast 96-Well Spectral Calibration Plates WSYBR with Green Dye with a manufacturers' storage requirement of -15C to -25C c. One box (lot#2411212) of Applied Biosystems Fast 96-Well Spectral Calibration Plates with ROX Dye with a manufacturers' storage requirement of -15C to -25C 3. Record review on 05/15/25 of freezer temperatures revealed temperatures colder than -25C for 7 of 8 days a. 05/01/25 - documented temperature -25.4C b. 05/02/25 -

	documented temperature -25.4C c. 05/05/25 - documented temperature -25.2C d. 05 /07/25 -documented temperature - 25.2C e. 05/08/25 - documented temperature - 25.4 C f. 05/09/25 - documented temperature - 25.3C g. 05/12/25 - documented temperature - 25.1C 4. Interview on 05/15/25 at 09:30 am with TS #3 confirmed the findings above. IV. Based on a written laboratory policy and procedure, record review, and interview with technical supervisor #3 (TS #3), the laboratory failed to ensure humidity was maintained according to manufacturers' requirements for eight of 20 days. Findings include: 1. On 05/15/25, TP #3 confirmed the laboratory performed IEF (Isoelectric Focusing) testing to screen for neonatal and adult hemoglobinopathies. 2. Review of the laboratory's written "Hemoglobinopathy" policy and procedure stated, "5. The room must be within 17-27C and 20-80% humidity to perform testing ....". 3. Record review on 05/15/25 revealed documented humidity readings less than 20% for eight of 20 days. a. 01/08/25 - 19% b. 01/09/25 - 19% c. 01/21/25 - 19% d. 01/22/25 - 19% e. 01/23/25 - 19% f. 01/24/25 - 19% g. 01 /27/25 - 19% h 01/28/25 - 19% 4. Interview on 05/15/25 at 10:35 am with TS #3 confirmed the findings above. IV. Based on manufacturers' instructions, record review, and interview with technical supervisor #3 (TS #3), the laboratory failed to ensure room temperature was maintained according to manufacturers' requirements for 14 of 20 days. Findings include: 1. On 05/14/25, TS #3 confirmed the laboratory performed IRT (human immunoreactive trypsin) testing using the GSP Neonatal IRT Kit. 2. Review of manufacturers' instructions "ASSAY PROCEDURE" stated, "Samples and plates must be brought to room temperature (+19-+25 C) before use ....". 3. Record review on 05/15/25 of documented room temperatures revealed temperatures below 19 C for 14 of 20 days a. 01/03/25 - 18.6C b. 01/06/25 - 18.6C c. 01/07/25 - 18.6C d. 01/08/25 - 18.1C e. 01/09/25 - 18.5C f. 01/14/25 - 18.9C g. 01/15 /25 - 18.6C h. 01/16/25 - 18.9C i. 01/21/25 - 18.1C j. 01/22/25 - 18.0C k. 01/23/25 - 18.5C l. 01/24/25 - 18.3C m. 01/27/25 - 18.0C n. 01/28/25 - 18.1C 4. Interview on 05 /15/25 at 11:35 am with TS #3 confirmed the findings above. V. Based on manufacturers' instructions, record review, and interview with testing person #6 (TP #6), the laboratory failed to document an incubator temperature for one of two patients. Findings include: 1. On 05/15/25, TP #6 confirmed the laboratory performed galactose-1-phosphate uridyl transferase (GALT) testing using the GSP Neonatal GALT assay. 2. Review of manufacturers' instructions (page 11) "ASSAY PROCEDURE" stated, "4. Incubate at +37C (+35 - +39C) for 3 hours 30 minutes without shaking". 3. Record review on 05/15/25 revealed no documented incubation temperature for one of two patients a. Patient #20250211111 - specimen collected on 01/17/25 received in the laboratory on 01/17/25 and test reported on 01/22/25 4. Interview on 05/15/25 at 12:42 pm confirmed the findings above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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: Based on observation and interview with testing person #3 (TP #3), the laboratory failed to ensure expired testing supplies were not available for use for one of one lot of pH (figure expressing the acidity or alkalinity) paper. Findings include: 1. On 05/15 /25, TP #3 confirmed the laboratory used pH paper for IEF (Isoelectric Focusing) testing to screen for neonatal and adult hemoglobinopathies. 2. Observation on 05/15

	/25 at 08:35 am, revealed one dispenser of expired pH paper (Lot# 234921 expiration date 12/15/2024). 3. Interview on 05/15/25 at 08:40 am with TP#3, confirmed the findings above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's package insert, maintenance records, direct observation, and interview with General Supervisor (GS) #4, the laboratory failed to follow the Hologic Aptima Panther manufacturer's instructions for daily mag wash cleaning for four of four months reviewed in 2025 as evidenced by: 1.In review of the manufacturer's instructions for the Hologic Panther on pg 200. Under Mag Wash Clean states, "The Mag Wash Clean maintenance task removes deposits that can build up inside the aspirators and associated tubing ...It is required that this task be performed daily after each testing day. For examples, if processing test orders on Monday-Friday, schedule the Mag Was Clean task to be run after working hours on Monday-Friday." 2. In review of the laboratory's maintenance checklist from January 2025 to April 2025, the following days did not have Mag Wash cleaning daily: Serial # 01068 January 2nd-3rd, 6th, 8th-10th, 13th, 15th-16th, 20th-23th, 27th-31st February 4th-5th, 7th, 10th-13th, 17th-20th,24-28th. March 3-5th, 7th,10-12th, 14th, 17th-20th, 24nd-27th. April 1st-3rd, 7th-10th, 14-16th, 18th, 21st-23nd, 25th, 28-30th. Serial #10178 January 2nd, 6th-10th, 14th-16th, 20th-23rd, 27th-30th. February 3rd-6th, 10th-13th, 17th-20th, 24th-27th. March 3rd-6th, 10th-13th, 17th-20th, 24nd-27th. April 1-3rd,7th-10th, 14-17th,21st-25th,29th,30th. 3.In direct observation of the two panther systems (01068 and 10178) at 1201 on 5-13-2025, both instruments were set for weekly maintenance for the Mag Wash.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on the review of the molecular laboratory quality management procedure, review of the molecular laboratory instrument comparison records, and interview with testing personnel (TP) #16, the laboratory failed to evaluate the relationship between multiple Applied bio systems Quant Studios 5 (QS5) analyzers every 6 months for SAR-COV-2 molecular testing. Finding Included: 1. The quality management procedure for the Molecular laboratory, under instrument comparisons states, "where multiple instruments or platforms are used to test for a given analyte, instruments / platforms must be compared against one another at least every 6 months to ensure comparability of results on the separate instruments". 2. On May 14, 2025 at 2:10 pm, review of the molecular laboratory comparison records for SAR-COV-2 revealed, comparisons studies were evaluated on the following dates: a. Serial numbers,

	272523023, 272527319, 272527312, 272524389, 272524070, 272527316 and 272523027 on January 25, 2024. b. Serial numbers, 272524969, 272523027 and 272523023 on April 17, 2025. 3. By interview on May 14, 2025 at 2:20 pm, TP#16 confirmed the Quant Studios 5 analyzers in use were not evaluated to each other every 6 months.