Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0627147	03/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Curry Hlth Dist Dba Curry General Hospital	94220 Fourth Street, Gold Beach, OR	

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
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 the Sysmex 660 coagulation analyzer manitenance records and interview with the Technical Supervisors (TS), also the General Supervisors (GS) on the current CMS 209 form, (TS/GS #1 & TS/GS #2), the laboratory failed to ensure the Sysmex 660 had weekly maintenance performed consistently in 2024 and 2025. Findings include: 1. Upon review of the written maintenance records for the Sysmex 660 coagulation instrument, used to monitor coagulation therapy and other inherited coagulation disorders, by assessing the Protime/ International Ratio calculation (PT /INR) and the Partial Thromboplastin Time (PTT), the laboratory failed to ensure that weekly instrument maintenance, as listed on the written monthly maintenance logs presented for review during survey, was performed weekly in 2024 and 2025. 2. Maintenance records were reviewed for February and January 2025 and January through December 2024. 3. Eleven (11) out of fourteen (14) months lacked at least one week where weekly maintenance failed to be performed and documented. Some months included a fifth (5th) week, which was also left blank. 4. Failure to perform and document on the written weekly maintenance log for the Sysmex 660 Coagulation instrument was noted as follows: Feb. 2025 no weekly maintenance Jan. 2025 no weekly maintenance Dec.2024 3 out of 5 weekly maintenance performed Nov. 2024 3 out of 5 weekly maintenance performed Oct. 2024 3 out of 5 weekly maintenance performed Sept. 2024 4 out of 5 weekly maintenance performed July 2024 3 out of 5 weekly maintenance performed June 2024 2 out of 5 weekly maintenance performed May 2024 3 out of 5 weekly maintenance performed April 2024 4 out of 5 weekly maintenance performed March 2024 4 out of 5 weekly maintenance performed 5. Request for the Operator's manual for the Sysmex 660 coagulation instrument

	revealed the laboratory was not in possession of a current Operator's manual. The TS /GS #1 and #2 produced a Sysmex 600 Operations manual for review. Due to the lack of a current Sysmex 660 coagulation instrument Operations manual, this surveyor was unable to determine the manufacturer's current recommendation for weekly maintenance. 6. Upon request for the Standard Operation Procedure (SOP) for the Sysmex 660 Coagulation instrument, it was revealed that the laboratory failed to ensure the laboratory's SOP included detail on the requisite weekly maintenance required for the Sysmex 660 coagulation instrument, as established by the laboratory and demonstrated on the written monthly maintenance log presented for review during survey. 7. Interview with TS/GS #1 and #2 at 11:15 am on 03/12/2025 confirmed the vacant maintenance spaces on the monthly maintenance logs for February and January 2025 and January - December 2024 and the lack of weekly maintenance for eleven (11) out of fourteen (14) months. 8. Interview with TS/GS #1 and #2 at 11:15 am on 03/12/2025, confirmed that the laboratory did not have a current Sysmex Operators Manual on site for the Sysmex 660 coagulation instrument, currently used for patient testing for PT/INR and PTT assays. 9. Interview with TS/GS #1 and #2 at 11:15 am on 03/12/2025 confirmed the facility's current SOP's for these coagulation assays lacked any instruction for in house definitive weekly maintenance requirements. 10. The Laboratory reports performing one thousand thirteen (1013) PT/INR and seven hundred forty (740) PTT assays annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of the Individual Quality Control Plans (IQCP's) submitted for review during survey, and also post survey via email 03/18/2025, 03/19/2025 and 03 /20/2025 and interview with the Technical Supervisors (TS) also General Supervisors (GS), TS/GS #1 and #2, the laboratory failed to ensure that the IQCP's in place at this facility included all three (3) required parts of an IQCP, were reviewed and approved by the Laboratory Director (LD) and reviewed at least bi-ennially by the LD, with written evidence of review. Findings include: 1. According to CFR 493.1256(d), an IQCP must contain three (3) parts which include a Risk Assessment (RA), a Quality Control Plan (QCP) and a Quality Assessment (QA) part. 2. Upon initial review of the IQCP's submitted for review during survey, it was revealed that the laboratory had hired a contract company to initiate the creation of the IQCP's for this facility. 3. The name of the contracted company of record was "QC made EZ - IQCP E-Optimizer". None of the eight (8) IQCP's reviewed for this facility revealed the location of this contracted company, so location or other information regarding this company is unknown. 4. Investigation via a search of the internet post survey revealed the company "QC made EZ - IQCP E-Optimizer" states their services as follows: "This IQCP Program provides the tools necessary to perform risk assessments and develop

QC plans unique to your laboratory and offers your laboratory flexibility to choose the tools that will best suit your needs". There was no mention of the QA development part of the IQCP that was easily found on line. 5. Upon review of the eight (8) IQCP's for this site, all of which were composed by the contracted company "QC made EZ - IQCP E-Optimizer", the following was revealed: a. The OSOM Sekisui Human Chorionic Gonadotropin (HcG) combo IQCP, composed by "QC made EZ - IQCP E-Optimizer" contracted service, lacked a QCP nor a QA part for this IQCP. Established date not available. Last reviewed by the LD 6/5/2017. b. Streptoccoccus pneumoniae antigen (urine) IQCP, composed by "QC made EZ - IQCP E-Optimizer" contracted service performed on the Alere instrument, established 08/16/2019, lacked a QCP and QA part for this IQCP. It was last reviewed by the LD 05/28/2021. c. The Chlamydia trachomatis and Neisseria gonorrhea IQCP assays, performed on the Cepheid GeneXpert instrument, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established 02/25/2019, lacked a QCP and QA part of this IQCP. Last review by the LD 05/28/2021. d. The Med-Tox instrument IQCP, for detection of twelve (12) drugs of abuse, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established date unavailable. The last date of review by the Laboratory Director (LD) was 05/07/2018. There was no evidence of QCP review or QA documentation for review while on site and as stated in the QCP and QA part of the IQCP, nor was any evidence submitted for review from the facility via email post survey. The following drugs of abuse are screened for using this instrument: AMP - Amphetamines BAR - Barbituates BZO - Benzodiazpines COC - Cocaine MaMP - Methamphetamine MTD - Methadone OPI - Opiates OXY - Oxycodone PCP - Phenyl Cyclohexyl Piperidine PPX - Propoxyphene TCA - Tri-cyclic Antidepressants THC - Tetrahydrocannabinol or marijuana e. The Clostridium difficile antigen test IQCP, composed by "QC made EZ - IQCP E-Optimizer" contracted service, using the Cepheid GeneXpert instrument, established 03/17/2018, and last reviewed by the LD 05/28/2021 stated no QC was out but no evidence of QCP review by the LD was evident. f. The Methicillin Resistant Staphylococcus aureus (MRSA) IQCP, composed by "QC made EZ - IQCP E-Optimizer" contracted service, using the Cepheid GeneXpert instrument, established 03/17/2018, and last reviewed by the LD 05/28/2021 stated no QC was out but no written evidence of QCP review by the LD was evident. g. The SARS-COV-2 plus assay IQCP, composed by "QC made EZ - IQCP E-Optimizer" contracted service, lacked a QCP and QA part of this IQCP. Established 06/08/2021 and last LD review dated 06/01/2024. h. The IQCP termed "4 plex", which included testing for four (4) different viral organisms including SAR-COV 2 (COVID), Influenza A & B, and Respiratory Syncytial virus (RSV) using the Cepheid GeneXpert instrument, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established 11 /22/2023, lacked a QCP and a QA part for this IQCP. Last reviewed and approved by the LD 06/01/2024. i. The Streptococcus pyogenes IQCP (termed Strep A) assay using the Cepheid GeneXpert instrument, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established 11/1/2023, lacked a QCP and a QA part for this IQCP. Last reviewed and approved by the LD 12/14/2023. j. Blood Gas analysis using the iSTAT instrument, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established 11/28/2022, lacked a QCP, a QA part for this IQCP nor a signed and dated approval page by the LD. k. The Basic Metabolic Panel (BMP) analysis using the iSTAT instrument, composed by "QC made EZ - IQCP E-Optimizer" contracted service, established 12/12/2022, lacked a QCP and a QA part of this IQCP and a signed and dated approval page by the LD. 6. The documents composed by "QC made EZ - IQCP E - Optimizer states through all eight (8) of these IQCP's, that the minimum QC required is that which is stated by the manufacturer. 7. Interview with TS/GS #1 and #2 on 03/12/2025 at 2:00 pm and in emails exchanged on 03/18/2025, 03/19/2025 and 03/20/2025, confirmed the above findings. 8. The

	laboratory reports performing the following number of tests annually for those tests listed above with IQCP's. a. SARS - COVID 2 283 assays annually b. 4 Plex for four viral infectious agents including COVID, Influenza A&B and RSV, 996 assays annually. c. Streptococcus pneumoniae antigen (urine) 690 assays annually. d. iStat Basic Metabolic Panel, 70 assays annually e. iStat Blood Gases, 11 assays annually f. Medtox panel for drugs of abuse 499 panels annually (12 tests each = 499 x 12 = 5,988 total assays) g. HCG serum 49 assays annually h. MRSA 254 assays annually i. C. difficile toxin 125 assays annually j. CT/NG 327 assays annually
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure (SOP) for receipt of microbiology media from multiple outside microbiology media sources and interview with the Technical Supervisor (TS), also the General Supervisor (GS), TS/GS #1, the laboratory failed to ensure that end user Quality Control (QC) was performed on all media shipments that contain microbiology culture media that are capable of determining organism differential reactions including hemolysis, fermentative abilities and inhibition of certain organisms. Findings include: 1. Upon request for written records demonstrating the laboratory performed end user QC with organisms that would indicate if the media was supporting growth of bacterial organisms, was performing as intended for differential, fermentative abilities and inhibitory reactions as intended, no written records could be produced. 2. Interview with TS/GS #1 at 12: 00 pm on 03/11/2025, confirmed that end user QC to ensure growth support, differential, fermentative and inhibitory activity of media designed to illustrate such, was not being performed on any microbiology media shipments when received in the laboratory, used in the diagnosis and treatment of patients with microbial infection. 3. The laboratory reports performing 10,244 microbiology cultures annually.