Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0628209	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lake District Hospital	700 South J Street, Lakeview, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 inspection of reagents available for patient use in the laboratory, the laboratory failed to ensure that all reagents being used for patient testing were not expired. Findings include: 1. Upon inspection of reagents available for use near the microscope used for reading microscopic urines, it was found that two vials of URINE CHEK urine adulterant strips had expired. One in October 2017 and one in February 2018. Additionally, an expired bottle of potassium hydroxide (KOH) was also found, with an expiration date of May 2019. 2. Upon inspection of the area used for cytology, it was found that the vials of PROTOCOL fixative had expired in January 2017. 3. The Technical Supervisor (TS) confirmed the expiration dates had been overlooked during interview 6/3/2019 at approximately 1430.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

	system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the iSTAT blood gas records and dicussion with the Technical Supervisor (TS), the laboratory failed to ensure the iSTAT instrument was calibrated every six (6) months. Findings include: 1. No evidence of Blood Gas calibration of the iSTAT instrument could be produced during the survey on 6/4/2019. 2. The TS verified during interview 6/4/2019 at approximately 1230 pm and later by email that the instrument had not been calibrated to her knowledge for five (5) years.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Microbiology Quality Control (QC) records and interview with staff, the laboratory failed to ensure QC was documented for the reagents/tests which require it. Findings include: 1. No written documentation for daily QC on Catalase, Coagulase, Indole or Cefinase could be provided. 2. No written documentation for weekly QC on gram staining could be provided. 2. The Technical Supervisor (TS) and testing personnel (TP) confirmed during an interview 6/4/2019 at approximately 12:00 that written documentation of the aforementioned reagents and tests did not exist.