

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0590260	(X3) Date Survey Completed 08/15/2023
Name of Provider or Supplier Salinas Valley Urology	Street Address, City, State 1115 Los Palos Dr, Salinas, CA	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the Biofire analyzer for microorganisms, review of 2021-2023 WSLH (Wisconsin State Laboratory of Hygiene) and laboratory proficiency testing (PT) records for Bacteriology, Parasitology, and Virology, the lack of signed Attestation statements, and interview with laboratory personnel, the Testing Person and Laboratory Director failed to attest to integrating PT samples into the routine testing of patients specimen. Findings included: 1. WSHL and laboratory proficiency testing records documented the laboratory's participation in proficiency testing 2021 - 2023. 2. The laboratory failed to provide for review Attestation statements signed by the Laboratory Director and Testing Person for 2022/events 1 and 3, and 2023/events 1 and 2. 3. Laboratory personnel affirmed (8/15/23 at 2pm) the aforementioned lack of signatures on the Attestation statement records. 4. The laboratory's compliance to test PT samples with the routine Biofire workload could not be assured. .</p>
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the Biofire test system and review of 2022 proficiency testing</p>

reports from CMS (report 155D, Individual Laboratory Profile) and WSHL, the laboratory failed to attain the overall score of 80% or better, constituting unsatisfactory testing in Bacteriology. Findings included: 1. The laboratory used the Biofire system to test for bacteria, as follows: a. Respiratory Panel Bordetella parapertussis Bordetella pertussis Chlamydia pneumoniae Mycoplasma pneumoniae b. GI Panel (Gastrointestinal) Campylobacter Clostridium difficile, toxin A/B Plesiomonas shigelloides Salmonella Vibrio Vibrio cholerae Yersinia enterocolitica E. coli (EAEC) E. coli (EPEC) E. coli (ETEC) E. coli (STEC) E. coli (EIEC) 2. CMS and WSHL reported the overall Bacteriology testing score for 2022/event 1 as 18%, signifying unsatisfactory testing for bacteria. 3. The reliability and quality of Bacteria results reported to patients could not be assured during the timeframe January 2022 through April 2022. The laboratory reported 2,900 Biofire results annually for Bacteria, Parasites, and Viruses combined (CMS116, 8/26/23). Six reports selected at random that included Bacteria results are as follows: Date ID ----- 1/11/22 AG22-4 1/14 22 AG22-6 2/09/22 AG22-15 2/16 /22 AG22-16 3/09/22 AG22-23 3/22/22 AG22-29 .

D2047

PARASITOLOGY
CFR(s): 493.829(a)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Based on observation of the Biofire test system and review of 2022 proficiency testing reports from WSHL, the laboratory failed to attain the overall score of 80% or better, constituting unsatisfactory testing in Parasitology. Findings included: 1. The laboratory used the Biofire system to test for parasites, as follows: a. GI Panel (Gastrointestinal) Cryptosporidium Cyclospora cayetanensis Entamoeba histolytica Giardia lamblia 2. WSHL reported the overall Parasitology testing score for 2022 /event 1 as 20%. 3. The reliability and quality of Parasite results reported to patients could not be assured during the timeframe January 2022 through April 2022. The laboratory reported 2,900 Biofire results annually for Bacteria, Parasites, and Viruses combined (CMS116, 8/26/23). Four GI Panel reports selected at random that include Parasites are as follows: Date ID ----- 1/14 22 AG22-6 2/16 /22 AG22-16 3/09/22 AG22-23 4/27/22 AG22-39 .

D2056

VIROLOGY
CFR(s): 493.831(a)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Based on observation of the Bio-Rad GeneFinder COVID-19 PCR test system and the BioFire test system, review of 2021- 2022 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and WSLH, the laboratory failed to attain an overall testing event score of 80% or better, constituting unsatisfactory testing in Virology. Findings included: 1. In 2021, the laboratory used the Bio-Rad GeneFinder PCR test system for COVID-19. a. WSHL reported the overall SARSCoV2-Molecular/Viral testing score for 2021/event 3 as 33% based on 2

unacceptable results (*) out of 3, as follows: PT Sample ID Lab Result Acceptable
----- CMW-4 Negative* Positive CMW-5
Negative Negative CMW-6 Negative* Positive b. The reliability and quality of
SARSCoV2 test results reported during the timeframe September - December 2021
could not be assured. The laboratory affirmed (by email on 8/24/23 at 11:54 am)
reporting 56,626 SARSCoV2 test results, of which only 31 were Positive. 2. The
laboratory used the Biofire system to test for viruses, as follows: a. Respiratory Panel
Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus
OC43 SARSCoV2 Human Metapneumovirus Influenza A Influenza B Parainfluenza
Virus 1 Parainfluenza Virus 2 Parainfluenza Virus 3 Parainfluenza Virus 4
Respiratory Syncytial Virus (RSV) b. GI Panel (Gastrointestinal) Adenovirus F 40/41
Astrovirus Norovirus GI/GII Rotavirus A Sapovirus 2. CMS and WSHL reported the
overall Virology testing score for 2022/event 1 as 18%, indicating unsatisfactory
testing for Viruses. 3. The reliability and quality of Virus results reported to patients
could not be assured during the timeframe January 2022 through April 2022. The
laboratory reported 2,900 Biofire results annually for Bacteria, Parasites, and Viruses
combined (CMS116, 8/26/23). Six reports selected at random that include Viruses are
as follows: Date ID ----- 1/11/22 AG22-4 1/14 22 AG22-6 2
/09/22 AG22-15 2/16/22 AG22-16 3/09/22 AG22-23 3/22/22 AG22-29 .