

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2258031	<b>(X3) Date Survey Completed</b>  07/31/2024
<b>Name of Provider or Supplier</b>  Heritage Labs	<b>Street Address, City, State</b>  1883 Hicks Rd, Rolling Meadows, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory proficiency testing (PT) records, email confirmation from America Proficiency institute (API), and interview with the Laboratory Director (LD), the laboratory failed to enroll in a sufficient number of proficiency testing challenges in 2024 for the microbiology subspecialty of virology. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the test menu, "Directory of Services", which indicated the laboratory performs Herpes Simplex Virus (HSV) testing under the microbiology subspecialty of virology. 2. Review of American Proficiency Institute (API) PT records revealed the laboratory failed to participate in three challenges containing five samples for each event in the subspecialty of virology. The laboratory was enrolled in molecular virology sexually transmitted infection (STI) panel which was received three times a year. Each STI panel contains two samples for herpes simplex virus 1 and herpes simplex virus 2. 3. Based on an email from an API representative on 07/31/2024 at 10:29 am confirmed that the laboratory was out of compliance for the subspeciality of virology in 2024 with the current enrollment in the STI panel. 4. Interview with the LD, on 07-31-2024, at 10:15 am, confirmed the laboratory failed to enroll in a sufficient number of virology challenges.</p>

## CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(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--

(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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, laboratory policy and procedures, and interview with testing personnel (TP) 1; the laboratory failed to follow the laboratory's quality control procedure for three of three patient test dates reviewed for Urinary Tract Infection (UTI) - Polymerase Chain Reaction (PCR) Panel testing, affecting 14 patients. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Ion-SOP-031 Quality Control Documentation", which stated: "Each batch will include an extraction [no template control] NTC (molecular grade water), Negative control (molecular grade water), and a positive control (master control included in the [Potentially Pathogenic Microorganisms] PPM kit)" 2. Review of laboratory procedures revealed the "Directory of Services" in DOC# ION-Form-013. This identified all analytes tested on the Urinary Tract Infection panel with antibiotic resistance markers (ARM). These included: Pathogens / analytes *Acinetobacter baumannii* (*A. baumannii*) *Klebsiella aerogenes* (*K. aerogenes*) *Enterobacter cloacae* (*E. cloacae*) *Enterococcus faecium* (*E. faecium*) *Escherichia coli* (*E. coli*) *Klebsiella pneumoniae* (*K. pneumoniae*) *Proteus vulgaris* (*P. vulgaris*) *Pseudomonas aeruginosa* (*P. aeruginosa*) *Streptococcus agalactiae* (grp B) (*S. agalactiae*) *Serratia marcescens* (*S. marcescens*) *Mycoplasma hominis* (*M. hominis*) *Ureaplasma urealyticum* (*U. urealyticum*) *Staphylococcus aureus* (*S. aureus*) *Enterococcus faecalis* (*E. faecalis*) *Klebsiella oxytoca* (*K. oxytoca*) *Morganella morganii* (*M. morganii*) *Proteus mirabilis* (*P. mirabilis*) *Citrobacter freundii* (*C. freundii*) *Staphylococcus saprophyticus* (*S. saprophyticus*) *Candida glabrata* (*C. glabrata*) *Candida tropicalis* (*C. tropicalis*) *Candida parapsilosis* (*C. parapsilosis*) *Candida albicans* (*C. albicans*) Antibiotic Resistance Markers / analytes included: Erythromycin ribosome methyltransferase B (ErmB) Methicillin-resistant *Staphylococcus aureus* (MRSA) gene (*mecA*) Beta-lactamase, Imipenemase (*bla-IMP-IMP-7*) Quinolone resistance gene A (*qnrA*) Quinolone resistance gene B (*qnrB*) Sulphydryl variable gene (SHV) Quinolone resistance gene S (*qnrS*) New Delhi Metallo-beta-Lactamase 1 (NDM-1) Oxacillinase-48 (OXA-48, *Bla OXA*) *Klebsiella pneumoniae* carbapenemase (KPC, *bla-KPC*) Verona integron-encoded metallo-beta-lactamase (VIM, *Bla-VIM*) Cephamycin resistance gene (FOX) Ampicillin resistance gene (AMPC) Azithromycin resistance gene (ACT) Erythromycin ribosome methyltransferase A (ErmA) Cefotaximase-Munich group 9 (CTX-M group 9) Cefotaximase-Munich group 1 (CTX-M group 1) Temoniera beta-Lactamase (TEM) Cefotaximase-Munich group 2 (CTM-M group 2) Vancomycin resistance gene A1 and A2 (*vanA1\_vanA2*) Sulphonamine resistance gene 2 (SUL2) Sulphonamine resistance gene 1 (SUL1) Vancomycin resistance gene B (*vanB*) 3. Review of laboratory quality control records for three of three patient testing dates (06/03/2024, 07/02/2024, 07/11/2024) for UTI PCR Panel found not every reported analyte / pathogen had both a positive and negative control utilized on each batch / day of

patient testing. UTI\_CTR3 was tested on 06/03/2024 with 7 patient samples and a negative control. UTI\_CTR3 contained the analytes: *S. agalactiae*, *S. aureus*, *S. marcescens*, *S. saprophyticus*, SHV, SUL1, SUL2, TEM, *U. urealyticum*, vanA1\_vanA2, vanB, VIM/ Bal-VIM. The missed analytes included: *A. baumannii*, ACT, AMPC, bla-IMP-IMP-7, *C. albicans*, *C. freundii*, *C. galbrata*, *C. parapsilosis*, *C. tropicalis*, CTX-M group 1, CTM-M group 2, CTX-M group 9, *E. cloacae*, *E. coli*, *E. faecalis*, *E. faecium*, ErmA, ErmB, FOX, *K. aerogenes*, *K. oxytoca*, *K. pneumonia*, KPC/bla-KPC, *M. hominis*, *M. morgani*, mecA, NDM-1, OXA-48/Bla-OXA, *P. aeruginosa*, *P. mirabilis*, *P. stuartii*, *P. vulgaris*, qnrA, qnrB, qnrS, UTI\_CTR2 was tested on 07/02/2024 with 2 patient samples and a negative control. UTI\_CTR2 contained the analytes: *K. aerogenes*, *K. oxytoca*, *K. pneumonia*, KPC/bla-KPC, *M. hominis*, *M. morgani*, mecA, NDM- 1, OXA-48/bla-OXA, *P. aeruginosa*, *P. mirabilis*, *P. stuartii*, *P. vulgaris*, qnrA, qnrB, qnrS. The missed analytes included: *A. baumannii*, ACT, AMPC, bla-IMP-IMP-7, *C. albicans*, *C. freundii*, *C. galbrata*, *C. parapsilosis*, *C. tropicalis*, CTX-M group 1, CTM-M group 2, CTX-M group 9, *E. cloacae*, *E. coli*, *E. faecalis*, *E. faecium*, ErmA, ErmB, FOX, *S. agalactiae*, *S. aureus*, *S. marcescens*, *S. saprophyticus*, SHV, SUL1, SUL2,TEM, *U. urealyticum*, vanA1\_vanA2, vanB, VIM/ Bal-VIM. UTI\_CTR3 was tested on 07/11/2024 with 5 patient samples and a negative control. UTI\_CTR3 contained the analytes: *S. agalactiae*, *S. aureus*, *S. marcescens*, *S. saprophyticus*, SHV, SUL1, SUL2, TEM, *U. urealyticum*, vanA1\_vanA2 , VanB,VIM/ Bal-VIM. The missed analytes included: *A. baumannii*, ACT, AMPC, bla-IMP-IMP-7, *C. albicans*, *C. freundii*, *C. galbrata*, *C. parapsilosis*, *C. tropicalis*, CTX-M group 1, CTM-M group 2, CTX-M group 9, *E. cloacae*, *E. coli*, *E. faecalis*, *E. faecium*, ErmA, ErmB, FOX, *K. aerogenes*, *K. oxytoca*, *K. pneumonia*, KPC/bla-KPC, *M. hominis*, *M. morgani*, mecA, NDM- 1, OXA-48/bla-OXA, *P. aeruginosa*, *P. mirabilis*, *P. stuartii*, *P. vulgaris*, qnrA, qnrB, qnrS, 4. On survey date 07-31-2024, at 12:00 pm, an interview with TP1 confirmed the laboratory failed to run all the analytes / pathogens for both positive and negative controls each batch / day of UTI PCR patient testing. TP1 also confirmed they were rotating between control lots for each batch / day of patient testing and not following the "Ion-SOP-031 Quality Control Documentation" procedure.