Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2088507	08/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
Healthquest Esoterics, Inc	6 Bendix, Irvine, 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
D0000	An on-site validation survey was conducted on 08/26/2026, with the following standard-level deficiencies cited:
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on DCA Vantage Hemoglobin A1C Individualized Quality Control Plan (IQCP) procedure review and staff interview, the laboratory failed to retain the Risk Assessment (RA) portion of the IQPC. Findings: 1. Review of the DCA Vantage Hemoglobin A1C IQCP procedure revealed the procedure lacked a Risk Assessment. 2. On 08/26/2026 at 12:30 PM, during an interview, the Technical Supervisor confirmed the laboratory could not locate the Risk Assessment portion of the DCA Vantage Hemoglobin A1C IQCP. 3. The laboratory reported performing 307 Hemoglobin A1C tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains,

	and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and staff interview, the laboratory failed to ensure its 1 of 1 procedure manual for performing complete blood count (CBC) differentials included step-by-step instructions for submitting slides for outside pathology consultation and defined criteria for when pathology review was required. Findings 1. On 8/26/26 at 12:00 PM, review of the procedure manual titled "Performing CBC Differential for Counting and Morphology" revealed the procedure lacked step-by-step instructions for submitting CBC slides for pathology review. The procedure also lacked defined criteria specifying when pathology review was necessary, for example, when blasts were identified on the slide. 2. On 8/25/26 at 12: 30 PM, during an interview, the Technical Supervisor confirmed the laboratory's procedure manual did not include instructions for submitting slides for pathology review and that the procedure did not specify that the presence of blasts on a slide required submission for pathology review. 3. The laboratory reported performing 114,650 CBC with differential tests annually.
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: Based on direct observation, review of manufacturer operating requirements, and staff interview, the laboratory failed to monitor and document temperature and humidity conditions in its 1 of 1 molecular amplification and its 1 of 1 storage room. Findings: 1. On 8/26/26 at 11:30 AM, during a tour of the molecular amplification room, the surveyor observed two Applied Biosystems QuantStudio 12K Flex Real-Time PCR instruments used for molecular amplification. No temperature or humidity monitoring log was present, and no temperature or humidity data was documented for the room. 2. Review of the Applied Biosystems QuantStudio 12K Flex manufacturer operating requirements showed a required operating room temperature of 15C to 30C (60F to 85F) and a relative humidity range of 20% to 80% (non-condensing). 3. On 8/26/26 at

	11:45 AM, during a tour of the storage room, the surveyor observed the following supplies with manufacturer-printed temperature storage requirements: 23 boxes of Diasorin DXI Wash Buffer II, requiring storage at 15C to 30C; 34 boxes of Diasorin Liaison XL Disposable Tips, requiring storage at 0C to 30C; 12 boxes of Diasorin Liaison XL Cuvettes, requiring storage at 0C to 30C; and 5 boxes of QuantiFERON-TB Gold Plus Blood Collection Tubes, requiring storage at 4C to 25C. No temperature monitoring log was present, and no temperature data was documented for the storage room. 4. On 8/26/26 at 12:00 PM, during an interview, the Technical Supervisor confirmed the laboratory was not monitoring or documenting temperature and humidity conditions in the molecular amplification room or the storage room. 5. The laboratory reported performing 6,125,600 tests annually.