

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2289968	(X3) Date Survey Completed 01/06/2026
Name of Provider or Supplier Telostrand Inventions Wv, Llc	Street Address, City, State 206 Main Street West, Suite A, Ronceverte, WV	
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 initial certification survey was conducted at Telostrand Laboratory WV, LLC on January 6, 2026, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficient practices cited are explained below.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, testing personnel (TP) records, lack of documentation, interview with the technical supervisor (TS1), and exit interview with the laboratory director, the laboratory failed to ensure a semi-annual (6 month) competency assessment was performed and documented for one of one testing personnel (TP1) in 2025. Findings: 1. Review of policies and procedures identified "SOP EMP003 Training Competency and Assessment" stating under 5. Frequency of Competency Assessment "Initial competency assessment within the first 90 days of employment and prior to independent testing" and "Additional competency assessments at 6 months and 12 months during the first year of employment". 2. Review of TP records revealed the following initial competency assessments for TP1: UroMiR PCa (miRNA) qPCR testing, laboratory director (LD) signed off 4/16/2025 Magmax Mirvana total RNA isolation kit (miRNA) , LD sign off 3/20/2025 Sexually Transmitted Infection (STI) panel testing Thermofisher multiplexed TaqMan gene expression assays., LD sign off 3/12/2025 Urinary Tract Infection (UTI) panel testing Thermofisher multiplexed TaqMan gene expression assays., LD sign off 3/7/2025 Omega Biotek Mag-Bind Universal Pathogen Core Kit DNA/RNA isolation kit (STI and UTI panels), LD sign off 2/28/2025 No semi-annual (6 month) competency</p>

assessments due in 2025 for TP1 could be located for the 5 methodologies used for testing in the laboratory. 3. During an interview, 1/6/26 at 9:30 am, TS1 verified the lack of semi-annual (6 month) competency assessments for TP1. 4. During the exit interview, 1/6/26 at 3:15 pm, the laboratory director confirmed the lack of semi-annual competency assessments for TP1 in 2025.

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 a tour of the laboratory molecular amplification testing areas, review of written policies and procedures, equipment manufacturer's instructions, lack of environmental monitoring equipment, lack of documentation, and interview with the technical supervisor (TS1), and exit interview with the laboratory director (LD), the laboratory failed to document the monitoring of (b)(2) temperature and (b)(3) humidity in two of two testing areas. Findings: 1. During a laboratory tour, 1/6/2026 at 10:48 am, the state surveyor observed two separate rooms with an established uni-directional workflow for preparation of reagents, preparation and processing of specimens, amplification testing, and storage of amplified specimens, with an Allsheng Auto-Pure 96 Nucleic Acid Purification system and QuantStudio 12k Flex Real-Time PCR testing platform identified as equipment in use for testing. The state surveyor could not locate a thermometer or hygrometer for the environmental monitoring of the ambient temperature and humidity for the equipment in the two separate testing rooms. 2. During an interview on 1/6/26 at 10:50 am, TS1 verified there was not a thermometer or hydrometer in the two separate rooms of the laboratory. 3. Review of laboratory policies and procedures identified "QM10- Temperature and Humidity Monitoring" stating "Ambient room temperature and humidity, refrigerator temperature, and freezer temperatures are monitored and documented electronically and/or manually daily in all areas of laboratory where testing is performed and/or reagents and specimens are stored." TS1 could not locate any documentation, electronic or manual, that the temperature and humidity had been monitored through date of survey. 4. Review of the Allsheng Auto-Pure 96 Nucleic Acid Purification system manufacturer's instructions for use identified temperature and humidity requirements as follows: a. Environmental temperature: 10-35 degrees Celsius b. Humidity: less than 70% 5. Review of the QuantStudio 12k Flex Real-Time PCR testing platform manufacturer's instructions for use identified temperature and humidity requirements as follows: a. Environmental temperature: 15-30 degrees Celsius b. Humidity: 20-80% 6. During exit interview on 1/6/26 at 3:15 pm, the laboratory director confirmed the lack of monitoring of the temperature and humidity in the two molecular testing rooms.