

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2270409	(X3) Date Survey Completed 10/22/2025
Name of Provider or Supplier Heristar Health Llc	Street Address, City, State 6550 Mapleridge St Ste 218, Houston, TX	
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	The laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an initial survey on 10/22/2025 and certification is recommended. Standard level deficiencies were cited.
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's sample receiving record log, patient final report, and confirmed in an interview, the laboratory failed to ensure normal reference intervals were available to health care providers for 3 of 3 condition screened for 1 of 1 patient final report reviewed. The findings were: 1. Review of the laboratory's sample receiving record log revealed the laboratory had received only 1 patient sample on 07/16/2025. 2. Review of the laboratory's patient final report revealed the laboratory failed to ensure normal reference intervals were available to health care providers for 3 of 3 condition screened for 1 of 1 patient final report reviewed. Collection Date:07/16/2025 Sample ID: 2530011P1DE Condition Screened Aneuploidies: Trisomy 21, Trisomy 18, Trisomy 13, Trisomy 15, Trisomy 16, Trisomy 22, 45X, 47XXX, 47XXY, and 47XYY. Results: Not detected Microdeletions: 22q11.2del, 1p36del, 4p16del, 5p15del,8q23q24del, 9pdel, 11q23q25del, 15q11.2-q13del, 18q22q23del, and 17p11.2del Results: Not detected Monogenic Conditions: Dominant monogenic conditions associated with 56 genes Results: Not detected 3. An interview on 10/22/2025 at 1:21 pm in a conference room, the laboratory director (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services</p>

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's CMS 116, CMS 209 form, the laboratory's personnel competency records, and confirmed in an interview, the technical supervisor failed to document the initial training for 3 of 3 testing personnel performing high complexity tests. The findings were: 1. Review of the laboratory's CMS 116 application revealed the laboratory was reactivated CLIA status on 06/06/2025. 2. Review of the laboratory's CMS 209 form, Laboratory Personnel Report (CLIA), signed by the laboratory director on 10/08/2025, revealed the laboratory identified 3 testing personnel performing high complexity tests. 3. Review of the laboratory's personnel competency records the technical supervisor failed to document the initial training for 3 of 3 testing personnel performing high complexity tests. Testing personnel #1 Hired date: 05/28/2019 Testing personnel #2 Hired date: 05/15/2019 Testing personnel #3 Hired date: 04/18/2022 3. An interview on 10/22/2025 at 10:55 am in a conference room, the technical supervisor (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services