

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2011324	(X3) Date Survey Completed 02/02/2023
Name of Provider or Supplier New Horizons Medical Pc	Street Address, City, State 186 Cedar Hill Street, Marlborough, MA	
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	A CLIA recertification survey was conducted for the New Horizons Medical, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. .
D2116	<p>TOXICOLOGY CFR(s): 493.845(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the College of American Pathologist (CAP) proficiency testing record review and interview, the laboratory failed to undertake appropriate remedial action in response to unsatisfactory proficiency testing results as evidenced by the following: a) A review of proficiency testing results for calendar years 2021 and 2022 (6 testing events) revealed that the laboratory obtained unacceptable scores. The following test event modules and specimens include but do not cover all unacceptable specimens noted: Drug Monitoring for Pain Management (DMPM) 1. 2021 modules: DMPM A specimens: DMPM-02 75% DMPM-03 75% DMPM B specimens: DMPM-05 33% DMPM-06 0% DMPM-07 33% 2. 2022 modules DMPM-A specimens DMPM-01 66% DMPM-02 66% Ethanol Biomarkers (ETB) 1. 2022 ETB-A 50% (2 specimen module) Urine Drug Adulterants (DAI) 1. DAI-A specimen DAI-06 50% for creatinine and pH. b) A review for each of the proficiency testing reports was completed by the technical supervisor. The reviews indicated that the problem with</p>

the unsatisfactory proficiency testing results was either data entry error into the CPA proficiency testing reporting system or mistranscription of the results into the same system. The reports included no documentation of any remedial action or retraining taken in response to the unsatisfactory results. c) The laboratory technical supervisor confirmed in an interview on 2/2/23 at 9:15 AM that no remedial action or retraining to correct the problem of data entry and mistranscription errors in response to unsatisfactory proficiency testing results had been undertaken. .

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:
Based on policy review and interview the laboratory failed to have and follow written policies and procedures to evaluate the competency of the technical supervisor as evidenced by the following: a) A review of employee competency records on 2/2/23 for four (4) laboratory personnel revealed that there was no competency assessment performed for technical supervisor #1. b) The technical supervisor confirmed in an interview on 2/2/23 at 9:00 AM that a competency assessment had not been completed on him. c) Review of competency policies and procedures on 2/3/24 revealed that there was no provision for evaluating the technical supervisor position.