

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2126206	(X3) Date Survey Completed 05/06/2021
Name of Provider or Supplier Haven Medical Group	Street Address, City, State 86 Baker Ave Extension, Concord, 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 Haven Medical Group laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review and interview, the laboratory failed to properly document the handling of proficiency testing samples as evidenced by the following: a) The laboratory is enrolled in American Proficiency Institute (API) proficiency testing. A review of proficiency testing records for calendar years 2019 and 2020 (4 testing events) revealed the fact that the program report forms and the attestation statements, provided by the proficiency testing program, were not maintained for all four (4) testing events reviewed. In addition, a copy of the program reports for each testing event was not available for three (3) of six (6) testing events (testing event 3 for 2019 and testing events 2 and 3 for 2020). b) The laboratory director interviewed</p>

on 5/6/21 at 9:05 AM confirmed that the program report forms and the attestation statements for the above events were not printed out and completed by the laboratory director and the laboratory technologist. .

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on record review and interview, the technical consultant failed to maintain documentation to verify the competency evaluation of the staff through review of proficiency testing and quality control records as evidenced by the following:
Proficiency Testing: a) The laboratory is enrolled in American Proficiency Institute (API) proficiency testing. A review of proficiency testing records for calendar years 2019 and 2020 (4 testing events) revealed the fact that the technical consultant failed to document a review of proficiency testing results for all four (4) testing events reviewed. Quality Control: b) A review of quality control records for calendar years 2019 and 2020 was performed. Documentation was not available to verify that the technical consultant regularly reviewed quality control data to ensure that personnel were following established quality control policies and procedures and to ensure the accuracy and reliability of patient test results. c) The technical consultant stated in an interview on 5/6/21 at 10:00 PM that proficiency testing and quality control records were being regularly reviewed, but the review was not being documented. .

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on interview, the technical consultant failed to ensure that the procedures for competency of the staff included assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for testing personnel as evidenced by the following: a) A request was made for employee competencies for calendar years 2019 and 2021. The technical consultant indicated in an interview on 5/6/21 at 9:55 AM that they had been performed but were not documented (refer to D6054). The technical consultant was asked if the annual competencies included some kind of blind sample testing and was told that only the laboratory technologist performed the proficiency testing samples. No other blind sample testing was performed by the technical consultant who also performs testing. .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the

performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on interview the technical consultant failed to document the annual competencies of individuals responsible for moderate complexity testing at least annually, after the first year as evidenced by the following: a) A request was made for employee competencies for calendar years 2019 and 2020. b) The technical consultant indicated in an interview on 5/6/21 at 9:55 AM that the competencies had been performed but had not been documented for the two laboratory personnel performing testing.