

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2006496	(X3) Date Survey Completed 08/15/2018
Name of Provider or Supplier Happi Health	Street Address, City, State 807 Franklin Street, Huntsville, AL	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure testing on PT samples was performed the same number of times as patient specimens. This was noted on seven of twenty-five surveys reviewed. The findings include: 1. A review of 2016 - 2018 API (American Proficiency Institute) PT records revealed TP #1, #2 and a previous testing personnel ran PT samples more than once as follows: A) 2016 Event #2 Hematology: all five specimens ran by TP #1 and then by TP #2 on 7/22 /2016 (submission cutoff date-8/5/16) B) 2016 Event #2 Microbiology: all five Clostridium difficile specimens ran by TP #1 on 5/25/16 and a previous testing personnel on 6/2/16 before the submission cutoff date of 6/3/16 C) 2017 Event #2 Chemistry: all five specimens ran by TP #1 on 5/24/17 and then by TP #2 on 5/23/17 before the submission cutoff date D) 2017 Event #3 Chemistry: all five specimens ran by TP #1 on 8/30/17, TP #2 and a previous testing personnel on 8/31/17 before the submission cutoff date E) 2017 Event #3 Hematology: survey specimens #11, #12 and #14 were run twice, and specimens #13 and #15 were run three times by the testing personnel before the submission cutoff date F) 2018 Event #1 Hematology: all five specimens ran twice by TP #2 before the submission cutoff date of 3/30/18 G) 2018 Event #2 Hematology: all five specimens ran twice by TP #2 before the submission cutoff date 2. In an interview on 8/15/2018 at 12:10 PM, when asked how many times patient samples are routinely run, TP #1 stated "Once". TP #1 was then asked why they were not treating PT specimens in the same manner as patient samples, TP #1 explained they had misunderstood the regulations requiring all testing personnel to perform proficiency testing. The surveyor clarified the regulations explaining surveys</p>

should be "rotated" among all personnel who perform patient testing. Thus, the above noted findings were confirmed. .

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on a review of the 2016 - 2018 API (American Proficiency Institute) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to document corrective action for four of eight Hematology surveys with results less than 100% (percent). The findings include: 1. A review of the API PT results revealed no documentation of investigation or corrective action for surveys with results less than 100% as follows: A) 2016-Event #2 Hematology with a score of 80% for Lymphocyte % and Monocyte %, resulting in an overall score of 87% for the WBC (White Blood Cell) Differential. B) 2017-Event #1 Hematology with a score of 80% for MPV (Mean Platelet Volume) C) 2017-Event #2 Hematology with a score of 80% for MPV (Mean Platelet Volume) D) 2017-Event #3 Hematology with a score of 80% for MCHC (Mean Corpuscular Hemoglobin Concentration) [NOTE: The surveyor also noted a lack of investigation and corrective action in Chemistry and Microbiology surveys, however the laboratory ceased testing in these specialties in 2018.] 2. In an interview on 8/15/2018 at 12:10 PM, Testing Personnel #1 was asked if the laboratory had performed and documented corrective action for the analytes with scores less than 100%. Testing Personnel #1 answered, "No", thus confirming the above noted findings. .

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on reviews of the Medonic Hematology analyzer calibration records, Quality Control (QC) records, and the Medonic Procedure Manuals, and interviews with Testing Personnel (TP) #1 and #2, the surveyor determined the laboratory failed to perform and document one of two 2017 calibrations, and failed to perform QC after two out of three 2017-2018 calibrations, as per manufacturer's instructions. The findings include: 1. A review of the Medonic CDS M Series Procedure Manual on page 7 revealed, "...CALIBRATION: Calibration must be performed upon setup of the instrument and then at a minimum of every six months...". 2. A review of the Medonic M Series User's Manual on page 62 revealed, "7.2 Calibration ... 18. It is

recommended to run controls after calibration to verify that all parameters have been calibrated correctly...". 3. A review of the Medonic Hematology analyzer records revealed calibrations were performed on 7/21/2016 at 9:09 AM and 8/23/2017 at 1:32 PM (more than one year after the previous calibration). There was no documentation of a calibration performed in early 2017. The surveyor also noted there was no QC performed and documented with the 8/23/2017 calibration, or with the 2/8/2018 calibration performed at 9:24 AM. 4. A review of the Hematology QC records revealed QC was only performed in the morning on 8/23/2017 from 8:50 to 8:56 AM, and on 2/8/2018 from 8:50 to 9:04 AM. There was no documentation of QC performed after the calibrations. 5. During an interview on 8/15/2018 at 1:15 PM, when asked if the laboratory performed a calibration in early 2017, TP #1 reviewed her records, and stated she had a note a calibration was performed on 1/16/2017; however, TP #1 was unable to provide documentation of the calibration. As the interview continued TP #2 was asked if she performed QC afterwards to verify the calibrations. TP #2 stated she believe she did, however the laboratory was unable to provide any QC performed after the 8/23/17 and 2/8/2018 calibrations. Thus the above noted findings were confirmed. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor