Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2011991	01/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Healing Corner, Llc	19115 W Capitol Dr, Ste 117, Brookfield, WI	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the laboratory director, the laboratory director did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for five out of five chemistry events in 2017 and 2018. Findings include: 1. Review of API (American Proficiency Institute) chemistry PT records show the laboratory director has not signed the attestation statements for two out of two events in 2017. 2. Review of ACP (American College of Physicians) Medical Laboratory Evaluation Program chemistry PT records show the laboratory director has not signed the attestation statements for three out of three events in 2018. 3. Interview with the laboratory director on January 22, 2019 at 10:30 AM confirms the director has not signed the attestation statements for five out of five chemistry events in 2017 and 2018. This is a repeat deficiency previously cited on September 9, 2015.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the laboratory director, the laboratory has not maintained a copy of instrument printouts for PT testing for one out of two chemistry PT events in 2017. Findings include: 1. Review of event one and event two of API (American Proficiency Institute) chemistry PT records from 2017 shows the record does not include Viva-E analyzer instrument printouts for the first chemistry event in 2017. 2. Interview with the laboratory director on January 22, 2019 at 10:30 AM confirms that the laboratory did not maintain instrument printouts from one out of two chemistry PT events in 2017.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of test records and interview with the laboratory director, the laboratory has not retained analytic records to show reagents were not used past their expiration date, or that calibrations were performed or verified and controls tested with reagent lot number changes on the Viva-E chemistry analyzer. Findings include: 1. Review of Viva-E analyzer records shows no historic records of previously used reagents, including lot numbers, expiration dates, or start and end dates of use. 2. Interview with the laboratory director on January 22, 2019 at 12:30 PM confirmed analytic system activity records were not retained for two years as specified in the requirements at 493.1252 through 493.1289. This is a repeat deficiency previously cited on January 28, 2014 and March 1, 2017.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the laboratory director, the laboratory did not maintain the chemistry PT result reports for one of three events in 2018. Findings include: 1. Review of events one, two, and three of the ACP (American College of Physicians) Medical Laboratory Evaluation Program PT records from 2018 shows the record does not include the result report from the PT provider for the second chemistry event in 2018. 2. Interview with the laboratory director on January 22, 2019 at 10:30 AM confirms that the laboratory did not maintain the chemistry PT result report for one of three chemistry events in 2018.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

	CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, observation of urine specimens, and interview with the laboratory director, the laboratory does not follow their written procedure for specimen labeling. Findings include: 1. Review of the "Urine Collection with Patient Instructions" procedure shows the procedure specifically states the container (cup) should be labeled with the patient identification information. 2. Observation on January 22, 2019 at 11:30 AM of urine specimens for toxicology testing show the specimen container lid is labeled with patient identification, with no patient information present on the specimen cup, for eleven out of eleven urine specimens. 3. Interview with the laboratory director on January 22, 2019 at 11:45 AM confirms the laboratory has not followed their procedure for specimen labeling. This is a repeat deficiency previously cited on March 1, 2017.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the laboratory director, the current laboratory director has not approved, signed, and dated procedures before use. Findings include: 1. Review of "QC Policy" and "Calibration, Calibration Verifications (AMR) (Analytical Measurement Range) and Assay Correlations" procedures in the laboratory manual shows no evidence of review and approval of the procedures by the current laboratory director. 2. Interview with the laboratory director on January 22, 2019 at 10:45 AM confirmed the current laboratory director has not approved, signed and dated the "QC Policy" and "Calibration, Calibration Verifications (AMR) and Assay Correlations" procedures. This is a repeat deficiency previously cited on March 1, 2017.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of the procedure manual and interview with the laboratory director, the laboratory did not document the date of discontinuance for procedures that are no longer in use. Findings include: 1. Review of the laboratory procedure

	manual showed no date of discontinuance for the venipuncture procedure. 2. Interview with the laboratory director on January 22, 2019 at 12:45 PM revealed the venipuncture procedure is no longer in use and the laboratory did not document the date of discontinuance. This is a repeat deficiency previously cited on March 1, 2017.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of maintenance records and interview with the laboratory director, the laboratory did not document quarterly maintenance for the Viva-E chemistry analyzer as required by the manufacturer for four out of four quarters in 2018. 1. Review of the 2018 Siemens Viva-E chemistry analyzer "Monthly/Quarterly /As Needed Maintenance" records showed no documented quarterly maintenance for four out of four quarters in 2018. 2. Interview with the laboratory director on January 22, 2019 at 11:30 AM confirmed the laboratory did not document quarterly maintenance for four out of four quarters in 2018. This is a repeat deficiency previously cited on January 28, 2014.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor comparison of previous CMS (Centers for Medicare and Medicaid Services) Form 2567 (Statement of Deficiencies and Plan of Correction) and deficiencies cited on the current Form 2567, review of proficiency testing (PT) reports, quality control (QC) records, patient result reports, laboratory procedure manual, package inserts, and interview with the laboratory director, the laboratory director did not provide overall management and direction in accordance with 493. 1445 of this subpart. Findings include: 1. The laboratory director did not maintain corrective actions to ensure compliance with previously cited regulations. See D6079. 2. The laboratory director did not sign PT result reports as reviewed. See D6091. 3. The laboratory director reported patient results when quality control values were not within acceptable limits. See D6097. 4. The laboratory director did not ensure approved procedures for the individual tests performed in the laboratory are available. See D6106. This is a repeat deficiency previously cited on January 28, 2014 and March 1, 2017.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor comparison of previous CMS (Centers for Medicare and Medicaid Services) Form 2567 (Statement of Deficiencies and Plan of Correction) and deficiencies cited on the current CMS Form 2567, and interview with the laboratory director, the laboratory director did not maintain corrective actions to ensure compliance with previously cited regulations. Findings include: 1. The following deficiencies have been cited on the CMS Form 2567 from prior surveys and are also cited on this CMS Form 2567: D2009: The laboratory director did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods, previously cited September 9, 2015. D3031: The laboratory has not retained analytic records to show reagents were not used past their expiration date, or that calibrations were performed or verified and controls tested with reagent lot number changes, previously cited January 28, 2014 and March 1, 2017. D5311: The laboratory does not follow their written procedure for specimen labeling, previously cited March 1, 2017. D5407: The current laboratory director has not approved, signed and dated procedures before use, previously cited March 1, 2017. D5409: The laboratory did not document the date of discontinuance for procedures that are no longer in use, previously cited March 1, 2017. D5429: The laboratory did not document instrument maintenance, previously cited January 28, 2014. D6076: CONDITION: Laboratory director responsibilities. The laboratory director did not provide overall management and direction in accordance with 493.1445 of this subpart, previously cited January 28, 2014 and March 1, 2017. D6097: The laboratory director did not ensure that patient test results were not reported when the test system was not functioning properly, previously cited January 28, 2014. D6106: The laboratory does not have approved procedures for the individual tests performed in the laboratory, previously cited on March 1, 2017. D6120: The laboratory director did not document competency evaluation of testing personnel, previously cited March 1, 2017. 2. Interview with laboratory director on January 22, 2019 at 12:45 PM confirms that the laboratory director did not maintain corrective actions to ensure compliance with previously cited regulations.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) reports and interview with the laboratory director, the laboratory director has not ensured PT reports received are reviewed to evaluate the laboratory's performance for four out of five PT events in

	2017 and 2018. Findings include: 1. Review of event one and event two API (American Proficiency Institute) chemistry PT reports from 2017 show the event two report has not been signed to indicate the results were evaluated. 2. Review of ACP (American College of Physicians) Medical Evaluation Program chemistry PT reports from the first and third event of 2018 show the laboratory director did not sign the reports to indicate the results were evaluated. The second event of 2018 was not available. 3. Interview with the laboratory director on January 22, 2018 at 10:15 AM confirms the laboratory director did not sign PT reports to show evaluation of the laboratory's performance for four out of five PT events in 2017 and 2018.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records for Ethyl Glucuronide (EtG), patient test results, and interview with the laboratory director, the laboratory director reported patient test results for EtG when the Viva-E chemistry analyzer was not functioning properly on October 30, 2018. Findings include: 1. Review of QC records for the Viva-E chemistry analyzer for EtG from October 30, 2018 shows the EtG High 1250 control result was "negative". The acceptable result is "positive". No evidence of corrective action was seen. 2. Review of patient results from October 30, 2018 shows EtG results were reported on seventeen patients. 3. Interview with the laboratory director on January 22, 2019 at 11:30 AM confirmed the EtG High 1250 control result was unacceptable on October 30, 2018, and seventeen patients had test results for EtG reported. This is a repeat deficiency previously cited on January 28, 2014.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, interview with the laboratory director, and review of manufacturer's package inserts, the laboratory does not have approved procedures for three of three individual tests performed in the laboratory. Findings include: 1. Review of the procedure manual show no procedures for amphetamine, ethyl glucuronide, or 6-acetylmorphine tests. 2. Interview with the laboratory director on January 22, 2019 at 12:45 PM revealed the laboratory uses the manufacturer's package inserts as the procedure for each individual test. 3. Review of the manufacturer's inserts shows no evidence of review or approval by the director prior to use for patient testing for three of three tests performed in the laboratory. This is a repeat deficiency previously cited on March 1, 2017.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)

	(7) The technical supervisor is responsible for 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; (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 surveyor review of laboratory records and interview with the laboratory director and human resources director, the laboratory director did not document competency evaluation of testing personnel in 2018. Findings include: 1. Review of laboratory records show no evidence that the technical supervisor (who is also the laboratory director) evaluated the competency of testing personnel, staff A, prior to staff A performing high complexity testing. 2. Interview with the laboratory director and human resources director, staff B, on January 22, 2019 at 12:45 PM confirms testing personnel, staff A, was hired in 2018 and the laboratory director did not document the evaluation of competency. This is a repeat deficiency previously cited on March 1, 2017.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of quality control (QC) records, instrument maintenance records, and interview with the laboratory director and human resources director, the laboratory did not retain documentation showing one of one new high complexity testing personnel met the qualification requirements for performing high complexity toxicology testing. Findings include: 1. The laboratory did not retain documentation showing one of one new high complexity testing personnel met the qualification requirements for high complexity toxicology testing. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or

medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on surveyor review of quality control (QC) records, instrument maintenance records, and interview with the laboratory director and human resources director, the laboratory did not retain documentation showing one of one testing personnel hired in 2018 met the qualification requirements for high complexity testing personnel. Findings include: 1. Review of toxicology QC records and Siemens Viva-E analyzer maintenance records shows staff A performed QC and maintenance from May 21, 2018 through August 22, 2018. 2. Interview with the laboratory director and human resources director (staff B) on January 22, 2019 at 12:45 PM confirmed that staff A performed high complexity testing from May 21, 2018 through August 22, 2018, and the laboratory did not retain documentation showing staff A was qualified to perform high complexity testing.