Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2132834	**(X3) Date Survey Completed** 01/22/2019
Name of Provider or Supplier Pursuit Of Hope, Pllc	**Street Address, City, State** 2315 East Mulberry Street, Angleton, 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 out of compliance with the CLIA regulations. The conditions not met were: D8100 - 42 C.F.R. 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to meet the requirements in 493.1773. (Refer to D8103)
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii)

Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:
Based on review of the CMS (Centers for Medicare and Medicaid Services) CLIA-116 database, surveyor observations, review of laboratory records, and confirmed in interview of facility personnel, the laboratory was not an active laboratory ready to perform non-waived chemistry testing. The findings were: NOTE: The facility was not performing patient testing at the time of the survey on January 22, 2019 and had never tested patient samples. 1. The definition of a laboratory at 42 CFR part 493.2 states the following; "Laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. 2. Review of the CMS-116 database revealed the laboratory would perform 108,000 chemistry tests annually. The laboratory's certificate of registration was effective from June 28, 2017 to June 28, 2019. 3. Surveyor observations of reagents, controls, and calibrators during the initial tour of the laboratory on January 22, 2019 at 09:20 hours revealed the following expired items in the refrigerator: Synermed Benzodiazapenes Reagent for IR500 Lot 1610160 Expiration Date: 04-30-2018 Synermed Buprenorphine Reagent for IR500 Lot 1612074 Expiration Date: 06-13-2018 Synermed Ecstasy Reagent for IR500 Lot 1707029 Expiration Date: 12-23-2018 Synermed Barbiturates Reagent for IR500 Lot 1701052 Expiration Date: 11-01-2018 Synermed Phencyclidine Reagent for IR500 Lot 1608083 Expiration Date: 02-22-2018 Synermed Opiates Reagent for IR500 Lot 1701112 Expiration Date: 09-17-2018 Synermed Methadone Reagent for IR500 Lot 1611056 Expiration Date: 05-19-2018 Synermed ETOH (Alcohol) Reagent for IR500 Lot 1703024 Expiration Date: 02-18-2018 Synermed pH Reagent for IR500 Lot 031417 Expiration Date: 03-31-2018 Synermed Urinary Creatinine Reagent for IR500 Lot 091701 Expiration Date: 01-09-2018 Synermed Cocaine Reagent for IR500 Lot 1701089 Expiration Date: 01-17-2018 Synermed Amphetamines Reagent for IR500 Lot 1610049 Expiration Date: 04-10-2018 Synermed Cannabanoid Reagent for IR500 Lot 1611118 Expiration Date: 05-22-2018 Synermed Oxycodone Reagent for IR500 Lot 1710142 Expiration Date: 11-13-2017 Synermed Methamphetamine Reagent for IR500 Lot 1701062 Expiration Date: 07-11-2018 Synermed DAU Control Kit (1 Box) Lot 1000 Expiration Date: 05-11-2018 pH 3.0 Calibrator (1 bottle) Lot 022117 Expiration Date: 03-20-2018 pH 110 Calibrator (1 bottle) Lot 022117 Expiration Date: 03-20-2018 Synermed Creatinine Calibrator 300 mg/dL Lot 121612-500 Expiration Date: 12-12-2017 Synermed Creatinine Calibrator 300 mg/dL Lot 121612-300 Expiration Date: 12-12-2017 Synermed Creatinine Calibrator 100 mg/dL Lot 121612-100 Expiration Date: 12-12-2017 Synermed Creatinine Calibrator 50 mg/dL Lot 121612-50 Expiration Date: 12-12-2017 ETOH Standards and Control 50 mg/dL Lot 081612-50 Expiration Date: 12-08-2017 ETOH Standards and Control 100 mg/dL Lot 081612-50 Expiration Date: 12-08-2017 ETOH Standards and Control 300 mg/dL Lot 081612-300 Expiration Date: 12-08-2017 ETOH Standards and Control Negative

Lot 081612-neg Expiration Date: 12-08-2017 Specimen Validity Kit for Urinary Creatinine Lot 1029 Expiration Date: 01-09-2018 Multi-Analyte DAU High Calibrator Lot 181705-97 Expiration Date: 05-18-2018 Multi-Analyte DAU Intermediate Calibrator Lot 111705-96 Expiration Date: 05-11-2018 Multi-Analyte DAU Cutoff Calibrator Lot 111705-95 Expiration Date: 5-11-2018 Multi-Analyte DAU Low Calibrator Lot 111705-94 Expiration Date: 05-11-2018 Multi-Analyte DAU Negative Calibrator Lot 1603180 Expiration Date: 01-11-2018 Lin-Zhi Norbupinephone DAU 3 ng/mL Calibrator Lot 1609008 Expiration Date: 02-28-2018 Lin-Zhi Norbupinephone DAU 5 ng/mL Calibrator Lot 1609009 Expiration Date: 02-28-2018 Lin-Zhi Norbupinephone DAU 7 ng/mL Calibrator Lot 1609010 Expiration Date: 02-28-2018 Lin-Zhi Norbupinephone DAU 10 ng/mL Calibrator Lot 1609011 Expiration Date: 02-28-2018 Lin-Zhi Norbupinephone DAU 20 ng/mL Calibrator Lot 1609013 Expiration Date: 02-28-2018 Lin-Zhi Norbupinephone DAU 40 ng/mL Calibrator Lot 1609014 Expiration Date: 02-28-2018 Lin-Zhi Norbupinephone DAU 75 ng/mL Calibrator Lot 1609015 Expiration Date: 01-11-2018 Synermed ETOH 30 mg/dL Control Lot 0816122 Expiration Date: 12-08-2017 Synermed ETOH 50 ng/dL Lot 0816121 Expiration Date: 12-08-2017 Lin-Zhi Cannabanoid DAU Calibrator 0 ng /mL Lot 1608002 Expiration Date: 01-20-2018 Lin-Zhi Cannabanoid DAU Calibrator 25 ng/mL Lot 1608005 Expiration Date: 01-20-2018 Lin-Zhi Cannabanoid DAU Calibrator 50 ng/mL Lot 1608008 Expiration Date: 01-20-2018 Lin-Zhi Cannabanoid DAU Calibrator 75 ng/mL Lot 1608010 Expiration Date: 01-20-2018 Lin-Zhi Cannabanoid DAU Calibrator 100 ng/mL Lot 1608011 Expiration Date: 01-20-2018 Key: ETOH - alcohol ng/mL - nanograms per milliliter mg/mL - milligrams per milliliter 38387 4. An interview with the facility representative on 01/22/19 at 0930 hours in the laboratory revealed the laboratory had a Synermed IR500 chemistry analyzer delivered in "early 2017." He stated that the facility had laboratory consultants to help with the validations. 5. Random review of the "validation study" available revealed verification studies (accuracy, precision, reportable range, and normal patient ranges) performed at the following laboratories in 2010: Synermed Select Partners, 17435 Tiller Court, Westfield Indiana Consultants in Pain Management, 11751 Gunbarrel Rd Suite G10, Chattanooga, Tennessee Ellis Pain Center, 1500 Lanfgord Dr. Building 200, Bugart, Georgia Rehabilitation and Pain Management, 1507 Hiewessee Road Suite 203, Orlando, Florida 6. Random review of the documentation available revealed the laboratory performed calibration on 4/05/17 and 11/13/17 for the Synermed IR500 chemistry analyzer. Amphetamine, lot 1610049, exp 4/10/18 Barbiturate, lot 171052, exp 7/9/18 Benzodiazepines, lot 16101610, 4/10/18 Buprenorphine, lot 1612074, 6/13/18 Cocaine, lot 1701089, exp 1 /17/18 Ecstasy, lot 160433, ex 10/21/17 Ecstasy, lot 1707029, exp 12/23/18 Alcohol, lot 1703024, exp 3/8/18 Methamphetamine, lot 1611056, exp 5/9/18 Opiate, lot 1701112, exp 7/19/18 7. Random review of the documentation available revealed the laboratory performed quality control on 4/5/17 and 11/13/17. MultiControl lot 1512084 (level 1) lot 1512086 (level 2) Buprenorphine lot 1511157 (level 2) lot 1511155 (level 1) Ecstasy lot 1508041 (level 2) lot 1508039 (level 1) Opiates lot 1211106R (level 1) lot 1601108 (level 2) 8. Review of the documentation available revealed no documentation of a verification study (accuracy, precision, reportable range, normal patient range) for the Synermed IR500 chemistry analyzer performed at the facility. 9. An interview with the facility representative on 01/22/19 at 0935 hours in the laboratory revealed the laboratory severed ties with their consulting group in August 2018. He stated that the consulting group came soon after and "picked" up the analyzer. 10. A tour of the facility on 1/22/19 at 0910 hours revealed no laboratory analyzer to perform non-waived testing. 11. Review of the laboratory records available revealed no documentation of training or competencies for any personnel. 12. An interview with the facility representative on 1/22/19 at 1005 hours in the

	laboratory confirmed the above findings. He stated that the laboratory hired outside consultants to perform the verification studies for the toxicology testing. He was unaware the laboratory had not finished the verification studies. He also stated that the facility never received their LCMS equipment to perform confirmation toxicology testing. 13. An interview with the facility CEO on 1/22/19 at 1030 hours in the office confirmed that the laboratory never performed patient testing and that the facility severed ties with the laboratory consulting group in 08/2018.