# Attachment 1 - STATEMENT of WORK (SOW)

Capillary Zone Electrophoresis

A. Purpose:

The purpose is to provide the necessary equipment, reagents, and consumables to perform the testing of the required tests listed in the Requirements section below.

B. Requirements:

1. Testing Menu required:

    a. Hemoglobin A1c performed on EDTA whole blood samples. No offline pretreatment is acceptable.
    b. Is able to perform % Carbohydrate Deficient Transferrin on Serum samples.
    c. Serum Protein Electrophoresis and ability to determine and identify/quantitiate abnormal gammopathies (immunotyping).

2. Testing Volume estimation based on previous year's workload:

    a. Hemoglobin A1c: 30,000 patient samples per year
    b. % Carbohydrate Deficient Transferrin: 100 patient tests per year
    c. Serum Protein Electrophoresis: 5,000 patient samples per year.
    d. Followup Immunotyping on positive protein electrophoresis: 2,000 patient samples per year.

3. Testing method Specifications:

    It is required that the technology to perform the assays (HbA1c, %CDT, and SPEP with Immunotyping) is capillary zone electrophoresis.

    a. Hemoglobin A1c method must be certifed by the National Glycohemoglbin Statndardization Program.
    b. Hemoglobin A1c must not have clinically significant interferences from HbC, HbS, HbE, HbD, and moderate elevations of HbF. Intereferences will affect the ability to provide consistently accurate results.
    c. Hemoglobin A1c must demonstrate an overal precision of less than 2% CV.
    d. Must be able to perform HbA1c testing at least 30 samples per hour directly from an EDTA collection tube.
    e. Testing method must be a direct measure of HbA1c with the calculation of %HbA1c based on measurement of HbA1c and $HbA_0$
    f. Carbohydrate deficient transferrin (CDT) is measured from serum to determine a history of chronic alcohol usage. %CDT is determined by the 2-sialo and 0-sialo fractions.
    g. Serum protein electrophphoresis and immunotyping:
        - Ability to separate major proteins into six fractions: albumin, alpha-1, alpha-2, beta-1, beta-1, and gamma globulins.
        - Automated electrophoresis with direct tube sampling
        - No interferences from triglyceride
        - Continuous sample loading with a throughput of a minimum of 60 samples per hour.
        - Automated Immunotyping for the identification of the monoclonals.
        - Overlay of reference pattern, control or patient curve to ease interpretation.

h. All calibrators, controls, and consumables are provided by the vendor.
i. Minimal reagent preparation. Reconsittution of controls, calibrators, and wash solutions is acceptable.
j. Capillary Zone Electrophoresis technology is preferred.

4. Equipment for testing shall include:

   a. Provision of a fully automated analyzer with the ability to perform the test menu listed in "1. Testing Menu" on a single instrument platform.
   b. Provision of an identical analyzer for full backup of testing.
   c. Instrument should be able to switch between tests automatically.
   d. Minimal daily, weekly, and monthly maintenance is required. No more than 10 minutes of hands-on time is to be required to perform daily maintenance.
   e. Ability to connect two instruments such that only one connection to the Laboratory Interface is necessary.
   f. All software, software updates, technical service, field service is provided at no additional charge to the VA.
   g. Printer is provided with each analyzer. Laser printer is preferred but not required.
   h. Standard electrical power requirement of 110 V with a maximum of 15 amps per analyzer is acceptable.
   i. All necessary hardware, analyzer, monitor, keyboard, mouse, computer, sample racks, are provided at no additional charge.
   j. Analyzer must be able to be placed on a table top.
   k. Results can be archived and retrieved from the analyzer's computer. If the storage capacity is exceeded, provisions for downloading results to separate media, such as CD or DVD should be made available.

5. Operation:

   a. Analyzer has direct tube sampling with the ability to read the positive sample identification using the Laboratory's 10-digit Universal ID barcode label.
   b. Ability to accept primary tubes, 13X75mm and 13X100 mm, and accomodates short samples.
   c. Cap piercing ability for HbA1c testing mode.
   d. Stable calibration or infrequent calibration for HbA1c. A stable or infrequent calibration is defined to be at least 30 days calibration stability, unless a component is replaced or service is performed on the analyzer.
   e. Minimal daily, weekly, and monthly maintenance is required. No more than 10 minutes of hands-on time is to be required to perform daily maintenance.
   f. Ability to store qualtiy control and perform quality control analysis on the analyzer.

6. Connectivity:

   a. Compatible with the SFVAMC Laboratory interface using DataInnovations for the transmission of data.
   b. Ability to connect two instruments such that only one connection to the Laboratory Interface is necessary.

7. System Service/Support/software:

   a. Provides onsite operator training.
   b. Provides for factory training of one operator per analyzer, if avaialable.
   c. Service/troubleshooting is available Mon-Friday during normal business hours

d. The schedule for implementation or services/requirements described herein shall be completed no later than thirty (30) days after notice of award of the BPA with installation being completed al all sites by a minimal period of time to be determined at the time of award.

Period of Performance

The period of performance shall consist of a base period, followed by four (4) one-year options, which may be exercised at the discretion of the Government. The estimated period of performance is as follows:

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| Base Period: | October 1, 2018 to September 30, 2019 |
| Option Year 1: | October 1, 2019 to September 30, 2020 |
| Option Year 2: | October 1, 2020 to September 30, 2021 |
| Option Year 3: | October 1, 2021 to September 30, 2022 |
| Option Year 4: | October 1, 2022 to September 30, 2023 |