Abbott Diagnostic SARS-CoV-2 (COVID-19) Antibody FAQ Sheet

1) **What test method does PMH Laboratory, Inc. perform?**
   We are currently using the Abbott Diagnostic SARS-CoV-2 (COVID-19) IgG antibody test method. Their test method is performing a specificity of 99.6%. The University of Washington Medical School has been conducting their own outside studies and has publicly stated that "Diagnostically, this is one of the best tests we can offer". As of April 22, 2020, their test method is pending FDA approval, but we are offering this test in accordance with the public health emergency guidance EUA issued by the FDA on March 16, 2020.

2) **How is the test collected?**
   Serological tests use serum in the blood samples from individuals who are being evaluated for SARS-CoV-2 infections or may have been exposed to the virus. We currently provide the IgG method, but we will soon be offering the IgM test as well.

3) **What does my test result mean?**
   A positive serological result indicates that an individual has likely produced an immune response to the SARS-CoV-2 virus. A negative serological result indicates that an individual has not developed detectable antibodies at the time of testing. While there are variable factors, this could be due to testing too early in the course of COVID-19, the absence of exposure to the virus, or the lack of an adequate immune response, which can due to conditions or treatments that suppress immune function. Confirmation of infection with SARS-CoV-2 must be made through a combination of clinical evaluation and other applicable tests. Decisions about ongoing monitoring treatment or return to normal activities for patients being treated for suspected infection with SARS-CoV-2 should be made in accordance with guidance of public health authorities.

4) **What is the expected turnaround time?**
   1-3 days from the time the specimen is received.

5) **Why is collecting SARS-CoV-2 (COVID-19) laboratory testing data important?**
   Serological tests for SARS-CoV-2 are intended for individuals who may have had COVID-19 symptoms or asymptomatic and no longer symptomatic. The test determines the presence of antibodies to SARS-CoV-2, the virus that causes COVID-19, and help identify individuals who have been exposed to the virus. Understanding if an individual has developed the antibodies and a potential immune response can be useful in the determination of important decisions such as the ability for hospital staff to care for patients.

6) **Which types of group plans and health insurance are accepted for COVID-19 diagnostic testing?**
   Under the FFCRA Section 6001(a), as amended by section 3201 of the CARES Act, requires plans and issuers to provide coverage for the serological tests:
   - Serological tests for COVID-19 are used to detect antibodies against the SARS-CoV-2 virus, and are intended for use in the diagnosis of the disease or condition of having current or past infection with SARS-CoV-2, the virus which causes COVID-19. The Food and Drug Administration (FDA) currently believes such tests should not be used as the sole basis for diagnosis. FDA has advised the Departments that serological tests for COVID-19 meet the definition of an in vitro diagnostic product for the detection of SARS-CoV-2 or the diagnosis of COVID-19.14 Therefore, plans and issuers must provide coverage for a serological test for COVID-19 that otherwise meets the requirements of section 6001(a)(1) of the FFCRA, as amended by section 3201 of the CARES Act.
   - Section 6001(a) of the FFCRA provides that plans and issuers shall not impose any cost sharing requirements (including deductibles, copayments, and coinsurance), prior authorization requirements, or other medical management requirements for these items and services. These items and services must be covered without cost sharing when medically appropriate for the individual, as determined by the individual's attending healthcare provider in accordance with accepted standards of current medical practice.
   - Section 3202(a) of the CARES Act provides that a plan or issuer providing coverage of items and services described in section 6001(a) of the FFCRA shall reimburse the provider of the diagnostic testing as follows: 1. If the plan or issuer has a negotiated rate with such provider in effect before the public health emergency declared under section 319 of the PHS Act, such negotiated rate shall apply throughout the period of such declaration. 2. If the plan or issuer does not have a negotiated rate with such provider, the plan or issuer shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website, or the plan or issuer may negotiate a rate with the provider for less than such cash price. Section 3202(b) of the CARES Act also requires providers of diagnostic tests for COVID-19 to make public the cash price of a COVID-19 diagnostic test on the provider's public internet website.