



## Training Material – 07/23/20

### COVID-19 Rapid IgG & IgM Rapid Test Kit Information

Welcome to our team on assisting Americans to be informed regarding the dreaded Coronavirus. Antigens are proteins that are found on the surface of the pathogen. Antigens are unique to that pathogen. When an antigen enters the body, the immune system produces antibodies against it. Lymphocytes, a type of white blood cell, recognizes the virus antigen as being foreign and then produces antibodies that are specific to that antigen. Once the invading pathogen has been destroyed the immune response usually winds down. The rapid antibody tests inform providers and patients of which antibodies appear in the blood (if the patient has the virus - with or without symptoms) and/or had the virus ("can I go back to work?").

Please review each topic of documents in this folder to learn about our Rapid Antibody Fingerstick Tests which produce results in 10-15 minutes:

#### 1 - Training

#### 2 - Marketing

#### 3 - Enrollment

#### 4 - Ordering

#### 5 - Testing

#### 6 - Articles

**Insurance Payments.** To give you an idea of what providers might make, Medicare pays around \$25 for collection and around \$54 for testing. Other insurance carriers may pay more. We are not a billing company and make no representations as to potential revenue for healthcare providers or when they can bill in relationship to an EUA status.

**Manufacturers.** We have six manufacturers, Biohit (China - EUA), Healgen Scientific (China - EUA), , Oncosem (Turkey), Orient Gene (China), Premier Biotech (China - EUA) and Synttron Bioresearch (USA).

**Biohit Healthcare – EUA Issued!** Yale validated the sensitivity to be 94.9% and specificity to be 98.8%. Cost is **\$17.50**.

**Healgen Scientific – EUA issued!** ErasmusMC, an independent lab in the Netherlands, did a validation study and concluded the specificity of Orient Gene (parent company) is **100%**. The National Institutes of Health (NIH) and Japan also did independent validations with similar results! Cost is **\$17.95**.

**Oncosem** is a manufacturer from Turkey. Their testing of over 300 patients concluded the IgG specificity is 99.7%. Cost is **\$16.50**.

**Orient Gene** is the non-EUA version of Healgen Scientific. It is the exact same cassette in the sealed mylar bag. Healgen manufacturers under three names. The FDA issued the EUA for Healgen, therefore, a provider without a moderate CLIA# can order Orient Gene. Cost is **\$17.95**.

**Premier Biotech – EUA issued!** Stanford University did a validation study and concluded that the specificity is **99.5%** (3,300 case study). Johns Hopkins also validated the findings. Cost is **\$17.95**.

**Synttron Bioresearch** is a manufacturer in the USA!. Their testing of over 600 patients concluded the specificity is **97.7%** and the sensitivity is 89.4%. Cost is **\$16.50**.