Explanation Letter

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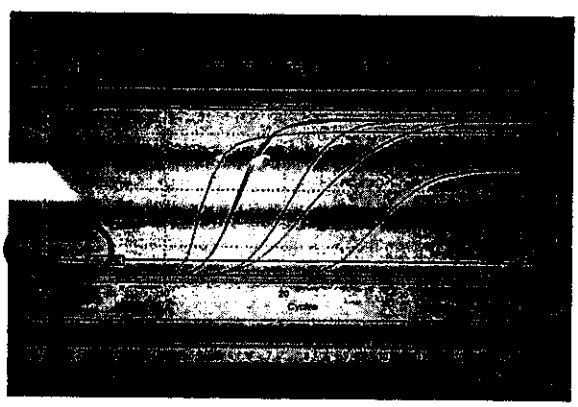
Doctor Jorge Yunda Machado, Alcalde de la Ilustre Ciudad de Quito
Subject: Explanation for Mexico testing institute test result for Isopollo® COVID-19 detection kit (real-time)

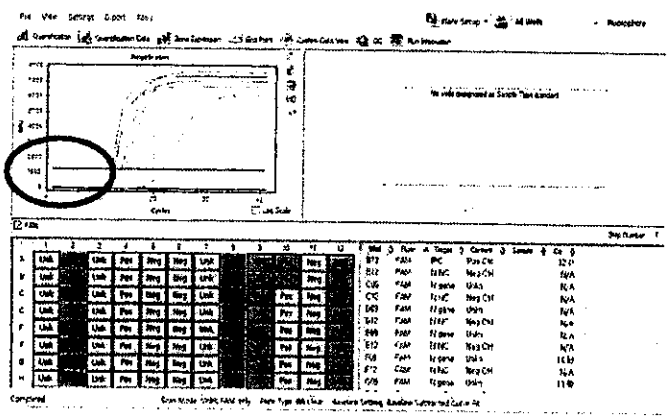
To whom it may concern,

1. The following is a explanation of the problem with the test result for our product, Isopollo® COVID-19 detection kit (real-time), tested by Mexican testing institution (Subsecretaria de Prevencion y Promocion de la Salud Direccion General de Epidemiologia Instituto de Diagnostico y Referencia Epidemiologicos).

2. Deteriorated Real-time PCR equipment: Mexico testing institution used CFX96 Touch Real-time PCR Detection System manufactured by BIO-RAD. In the preliminary test, the RFU Threshold value of Mexico testing institution was about 100 RFU as shown in the figure below while the RFU Threshold value tested by our side was about 1,000 RFU, which is more than 10 times. It is considered that the fluorescent lamp (FAM) was expired due to equipment aging. For this reason, we requested to conduct the test after performing OQ (Operational Qualification) Validation on this equipment, it is considered that a serious error was occurred because the test was conducted by the test equipment without validation.



(RFU Threshold value of Mexico test institution)



(RFU Threshold value of M monitor)

3. In addition, Virus Parainfluenza tipo1, Virus parainfluenza tipo3, and Influenza B were found to be specific to our product Isopollo® COVID-19 detection kit (real-time). In this regard, in silico analysis results of these viruses, Homology with Virus Parainfluenza tipo1 is 15% (R gene), 7% (N gene), and Homology with

Virus parainfluenza tipo3 is 0% (R gene), 0% (N gene) and Homology with Influenza B were 0% (R gene) and 0% (N gene). In order to have specificity with our products, all 6 Primers must have a Homology of 80% or more, and even if one Primer has a Homology of less than 80%, specificity does not occur. This eventually confirmed that there was very little Homology between these viruses and our products (if less than 80%, there is no Homology) (refer to Attachment #1). Therefore, it is considered that there is a serious error in the test data of the Mexico testing institute.

4. Problem of Standard material, AccuPlex SARS-CoV-2 (Seracare): The concentration of Accuplex SARS-CoV-2 standard material used by the Mexico testing institute was 5,000 copies/ml (5 copies/ul) (Attachment #2), and our sensitivity (LOD) was 50 copies/reaction (10 copies/ul). In this case, when determining the positive and negative of our products using the positive AccuPlex SARS-CoV-2 standard, all of them are negative because the concentration of the standard (5 copies/ul) is higher than our sensitivity (10 copies/ul). In this case, when determining the positive and negative of our products using the positive AccuPlex SARS-CoV-2 standard, all of them must be negative because the concentration of the standard (5 copies/ul) is higher than our sensitivity (10 copies/ul). However, all were positive, as shown in Table 4. Resultados del panel de tercera opinion on the Mexican report, which contradicts all negative results of Table 1. Verificacion de la sensibilidad on the Mexican test report. This is considered a serious error in the test and the tester is not qualified.

5. For your knowledge, our company has exported and scheduled for export more than 1,200,000 units in countries such as: Italy, Peru, Ecuador, Indonesia, United Kingdom where they have obtained their health registration, according to the characteristics presented in our insert (includes 99% of accuracy and 100% of specificity). Our production processes are of high quality because it has all the ISO certifications.

6. As a result of analyzing the report tested by the Mexican government agency, the above test error (No equipment aging and validation, inaccuracy of virus cross-reaction testing, and inappropriate use of standards) is considered insufficient for accurate verification of our products, and the reliability of the test institute is suspected.

7. In this regard, we are protesting to Mexican testing institutes, and for accurate verification of our products, this is a preliminary result that should be corrected. If Ecuador do this verification, we are requesting reliable domestic and Ecuadorian accredited testing institutes to conduct testing, with qualify equipment. Samples for testing will be provided upon request to an accredited Ecuadorian testing laboratory. We export around the world our product with any trouble, countries like Italy, Peru, Indonesia, United Kingdom use our products with excellent results. If you think is necessary we can send a Doctor to verify and make this test in your labs to warranty our tests.

8. We are requesting to international accredited testing institute, that have WHO approval to make testing

with the correct and qualify equipment, to confirm our accuracy and send you the results

9. To obtain the sanitary registration in Ecuador, all the documentation was sent by M Monitor to ARCSA, the same that is real and verifiable.

10. We sincerely apologize for this misunderstanding inconvenience caused, we and our local authorities are confidents about the quality and accuracy of our products, we guarantee the highest level of quality and performance through verification in order of our stably, the highest product quality and performance under our policy.

ncerely yours,

/o Sung Jeon / CEO
monitor Inc.