

15 June 2017

Tejas Kulkarni  
bioLytical Laboratories, Inc.  
1108-13351 Commerce Parkway  
Richmond, BC V6V 2X7  
Canada

Dear Tejas:

I am writing to inform you we have notified the Competent Authority in the following countries:

- **Italy**

With this notification, bioLytical Laboratories, Inc. has met the requirements of the In-vitro Diagnostics Directive, 98/79/EC for the following devices:

- **INSTI HIV-1/HIV-2 Antibody Test**
- **INSTI HIV Self Test**

As of today and without any further notice from the respective Competent Authorities, bioLytical Laboratories, Inc. can consider the respective devices as officially notified.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,



Rene van de Zande  
Director  
Emergo Europe



**Emergo Europe B.V.**

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*\* Self-Certify/Other IVD notification in The Netherlands with the Dutch Healthcare Inspectorate (IGZ) grants you access to: Austria , Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Switzerland, Sweden, and the United Kingdom.*

*After notification in the Netherlands, the following 3 countries still require additional notification for Self-Certify/Other: Belgium, Bulgaria, and Croatia. Please let us know bioLytical Laboratories, Inc. will require notification in any of the additional countries.*

*\* List A, List B and Self-Test IVD notification in The Netherlands with the Dutch Healthcare Inspectorate (IGZ) grants you access to: Austria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Liechtenstein, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Slovakia, Slovenia, Sweden, Switzerland, and the United Kingdom.*

*After notification in the Netherlands, the following 8 countries still require additional notification for higher IVDs: Belgium, Bulgaria, Croatia, Italy, Latvia, Portugal, Romania, and Spain. Please let us know bioLytical Laboratories, Inc. will require notification in any of the additional countries.*