



IDK® Validation Assistance Checklist

Thank you for choosing to work with Immundiagnostik, Inc. We look forward to helping your lab complete a successful validation so you can continue to expand your product offering.

This checklist will guide your team through every step of the IDK® assay validation assistance process.

Getting Started

- 1. Initial discovery call with IDK, Inc.'s Technical Applications Scientist (TAS) and lab personnel.
- 2. Lab provides:
 - a. Validation protocol
 - b. Will it be manual or automated?
 - c. What instruments and tools will be used to perform testing?
- 3. Speak with IDK, Inc.'s Business Development Manager (BDM) to discuss the project.
 - a. Quote will be provided to the lab
- 4. TAS will provide:
 - a. Appropriate assay file for the instrument.
 - b. Review recommendations if the test is performed manually.
- 5. TAS will discuss and determine if on-site or remote validation assistance is needed.
- 6. Lab will provide a PO for validation kits.
- 7. IDK, Inc. will order kits from Immundiagnostik AG (if not in stock) and ship to lab.

On-site Validation Assistance

- 1. If on-site validation assistance is needed, we will discuss a time that works for both parties.
- 2. Prior to arriving, TAS will confirm that the lab has all necessary samples for testing.
- 3. Once on-site, TAS will review the ELISA procedure with lab technician and ensure the proper techniques are used to perform the assay.
 - a. TAS will provide a Training Certificate of Completion to lab technician
- 4. TAS will help review and analyze data.

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On-site Validation Assistance (Continued)

- 5. If needed, TAS will train other lab technicians on the assay procedure.
 - a. TAS will review the results and answer any questions from lab technicians.
- 6. Lab will provide an estimated go-live date.
- 7. Prior to the go-live date, IDK, Inc.'s BDM will contact the lab to ensure they have enough kits and determine the projected volume to ensure that inventory is available.

Post-Validation

- 1. TAS will provide ongoing remote support to the lab.
- 2. TAS will help troubleshoot any problems that arise.
 - a. If needed, TAS will return to the lab for on-site support.

We're Here When You Need Us

Now that your validation is complete, remember that you can contact us anytime for further assistance from our technical support team.

 888-433-9020

 idsupport@immundiagnostik.com

 www.idkna.com