Ustekinumab Drug Level CLIA Kit

Instructions for Use (IFU)

For Research Use Only in the United States and Canada

REF **80-UKDHU-FC100**

Manufactured By:
ALPCO
26-G Keewaydin Drive
Salem, NH 03079

Customer Service:
Tel: (603) 893-8914
Tel: (800) 592-5726
e-mail: cs@alpco.com

Intended Use

The Ustekinumab Drug Level CLIA Kit is a chemiluminescent immunoassay for the quantitative determination of free ustekinumab concentration using the KleeYa platform. Ustekinumab is a therapeutic antibody against the p40 subunit of IL-12 and IL-23. Stelara® is the brand drug marketed by Janssen Pharmaceuticals. For Research Use Only in the United States and Canada. Not for use in diagnostic procedures.

Principles of the Procedure

The Ustekinumab Drug Level CLIA Kit is a chemiluminescent immunoassay system with detection based on the use of a monoclonal antibody against ustekinumab (Stelara®). The KleeYa system allows for complete automation of immunoassays. It performs the sample processing (sample dilution, sample and reagent dispensing, incubations, wash processes) as well as the measurement and evaluation. An anti-ustekinumab monoclonal antibody is coated onto the magnetic beads. Re-calibrators, controls and samples are incubated. Ustekinumab drug in the sample is bound by the capture antibody conjugated to the surface of the magnetic beads. After a washing step, a chemical-conjugated secondary monoclonal antibody detects the ustekinumab bound to the antibody-coated magnetic beads. After incubation and an additional wash step, a substrate is added. Upon reaction, a flash of signal is directly read on the KleeYa instrument. The intensity of the light is proportional to the amount of conjugate bound, and thus to the amount of captured ustekinumab. Concentration of ustekinumab in the samples is calculated on the instrument based on the calibration curve as determined by the re-calibrators run within a 24-hour period.

Kit Concept

The Ustekinumab Drug Level CLIA Kit is specifically designed for automated analysis using the KleeYa instrument. To perform analysis on the instrument, carefully follow maintenance and operating instructions in the KleeYa user manual.

Reagents Supplied for 100 Tests: Ready to Use. Store at 2-8˚C. Do not freeze.

1 x REAGENT CARTRIDGE	**Magnetic Beads** 1 vial of magnetic beads conjugated with a monoclonal antibody. Ready to use.	1 x 5 ml
	Conjugate 2 vials with the diluted anti-Ustekinumab Detector Antibody. Ready to use.	2 x 10 ml
	Assay Buffer 2 vials of Ustekinumab Assay Buffer. Ready to use.	2 x 10 ml
1 x ANCILLARY CARTRIDGE	**Assay Buffer** 3 vials of Ustekinumab Assay Buffer. Ready to use.	3 x 10 ml
1 X RE-CALIBRATORS and CONTROLS	**Re-calibrator 1 and 2** 2 vials, each containing Ustekinumab at a fixed concentration. Ready to Use.	2 x 1 mL
	Control 1 & 2 2 vials, each containing Ustekinumab at a fixed concentration. Ready to Use.	2 x 1 mL

The range of acceptable values for each control level are printed on the lot-specific Certificate of Analysis.

Ancillary Materials

*USB Storage Device (10-CLUSB-01)

*Each kit shipment includes a Universal Serial Bus (USB) Storage Device containing the Definition file (a parameter file defining all the automated steps of the assay). The data from the USB Storage Device is uploaded onto the KleeYa via the USB port prior to performing the assay on a KleeYa instrument for the first time. Please refer to the instructions enclosed with the USB Storage Device (10-CLUSB-01) for loading of assay files.

Additional Materials Required but Not Provided

ALPCO Product #	Item Name	Pack Size
15-10111184	KleeYa Trigger Pack: 3 sets of trigger solutions	3,000 tests
15-10111002	Wash Buffer 5X	4 x 2 L
15-10033666	Stackable Cuvettes; 1,000 µL	3,000 cuvettes
15-10036506	Disposable Anchor Tips; 300 µL	5,760 tips
	Distilled or Deionized Water	
	KleeYa Platform	
	General laboratory equipment	

For Sample Collection and Processing:

- Serum collection tubes
- Centrifuge capable of 1,000 to 2,000 x g (see specifications for serum collection tube) with refrigeration to 4°C
- Sample vials and labels
- Calibrated pipette and pipette tips

Precautions and Warnings

1. **For Research Use Only in the United States and Canada. Not for use in diagnostic procedures.**
2. The human blood products incorporated into this kit have been tested for the presence of HIV (Human Immunodeficiency virus), HBV (Hepatitis B virus), and HCV (Hepatitis C virus). Test methods for these viruses do not guarantee the absence of a virus; therefore, all reagents should be treated as potentially infectious. Handling and disposal should be in accordance with all appropriate national and local regulations for the handling of potentially biohazardous materials.

3. All materials derived from animal sources are BSE negative. However, all materials should be treated as potentially infectious.

4. Re-calibrator and controls may only be run with lot corresponding reagents. If purchased separately, the lot number for the re-calibrator and control set (80-UKDHU-FCSET) must match the lot number for the reagent kit (80-UKDHU-FC100) being run.
5. Re-calibrators and controls and samples in skirted 2mL microcentrifuge tubes may only be loaded into a KleeYa sample rack containing white spacers. Contact ALPCO technical support for information on other tube types.
6. Routine maintenance of the KleeYa instrument is required for proper performance.
7. Some reagents contain ProClin 300 or Bronidox (< 0.10%) as a preservative agent.
8. Additional safety information on hazardous substances included in the kit and actions to take in the event of direct contact or ingestion is provided within the Safety Data Sheet (SDS) for this product. To obtain an SDS, please contact our customer service department at (800) 592-5726 or email: ts@alpco.com.
9. Dispose of unused reagents according to local and federal regulations.

Storage and Transport Conditions

1. Reagents are shipped on cold packs but do not require specific temperature control. Reagents should be stored at 2-8°C. Unopened reagents are stable until the expiration date on the box label. **Do Not Freeze.**
2. The expiration date is printed on all component labels.
3. When cartridges are not in use, it is recommended they are stored at 2-8ºC.

Reagent Stability

Reagent and Ancillary Cartridges
Store at 2-8ºC. Unopened cartridges are stable until the expiration date printed on the label. Opened cartridges are stable for up to 28 days if stored at 2-8˚C.
Re-calibrator and Controls
Store at 2-8ºC. Unopened re-calibrator and controls are stable until the expiration date printed on the label. After opening, re-calibrator and controls are stable for up to 4 uses within 28 days if stored at 2-8˚C.

Reagent Preparation

1. Reagent and ancillary cartridges are ready to use. The KleeYa instrument will automatically recognize the cartridges and mix bead solutions and will maintain reagents at 8-10°C.
2. Controls and re-calibrators are provided in a ready-to-use liquid format. Mix by gentle inversion and load in appropriate KleeYa sample racks with white spacers. Ensure no bubbles are present after mixing. If necessary, assign the lot specific assay to the appropriate control(s) on the KleeYa instrument. Deselect the default sample dilution in the dilution tab for the controls.

Note: Caps must be placed on the correct vials after each use. Switching caps for the re-calibrator and controls can negatively impact results.

Sample Collection and Storage

Human serum samples are appropriate for use in this assay. No pre-treatment of the sample is required. Follow local and national guidelines for the handling of potentially infectious samples.

Collect serum using standard venipuncture procedures. Immediately following collection, invert tube ten times. Allow the blood to clot at room temperature for 30 minutes.
Within 30–60 minutes of collection, centrifuge balanced tubes at the speed and time recommended for the collection tube used at 4°C. Following centrifugation, carefully pipette the serum layer only into a fresh labeled tube. Please consult ALPCO technical support regarding tube compatibility with the KleeYa system.

Serum samples are stable at room temperature or 2-8˚C for up to 7 days from time of collection. Freeze at ≤−20°C for longer storage[1]. If thawed from ≤−20°C, an additional centrifugation step at 3,000 x g for 5-10 minutes at 4°C should be completed to remove any insoluble protein or lipid aggregates that may form. Following centrifugation, carefully pipette the serum layer only into a fresh labeled tube and discard any pellet that may form.

Briefly vortex samples (2-5 seconds) before testing.

Assay Procedure

1. Tap on the Load button in the main menu bar to show the Load screen.
2. Tap on the Samples button below the Load button.
3. Load all re-calibrator, control, and sample tubes into sample rack(s).
4. Load the sample rack(s), one after the other, into the sample loading bay
5. If necessary, assign desired tests for each sample and control.
6. Tap on the Reagents button below the Load button.
7. Load all necessary Reagent Cartridges into reagent rack(s).
8. Load the reagent rack(s), one after the other, into the reagent loading bay
9. Load cuvettes, tips, and solutions and empty waste as required to complete the run.
10. Tap on the Start button to start the test run.

    NOTE: Any additional information can be found in the KleeYa user Manual.

Assay Calibration and Quality Control

1. Re-calibrator 1 and 2 must be run each day Ustekinumab drug level testing is performed.

2. Control 1 & 2 are to be run each day Ustekinumab drug level testing is performed. Ustekinumab drug level control results reported by the KleeYa software must be multiplied by 10 prior to comparison to the control range reported in the lot-specific Certificate of Analysis provided with each kit.

3. Traceability: No international reference material or reference measurement procedures are available for ustekinumab. The Calibrators and Controls used in the Ustekinumab CLIA Kit are traceable to internal reference standards made from the branded Stelara® therapeutic antibody.

Calculation of Results

The Ustekinumab Drug Level CLIA Kit results are directly analyzed in the KleeYa software. The concentration of ustekinumab in the samples is calculated on the instrument via the calibration curve as determined by the re-calibrators within a 24-hour period. Results can be exported locally to a USB device.

References

1. Scheffe, N. et al. (2020). Development of a Mass Spectrometry-Based Method for Quantification of Ustekinumab in Serum Specimens. Ther. Drug Monit, 42:572-577. *DOI:* 10.1097/FTD.0000000000000734.

Symbols Glossary

Product reference or catalog number

Batch or lot number

Temperature limitation: store at 2 to 8°C


Expiration or use by date


Consult instructions for use

Manufactured by:
ALPCO
26 Keewaydin Drive, Unit G
Salem, NH 03079

Customer service:
Tel: (603) 893 – 8914
Tel: (800) 592 – 5726
e-mail: cs@alpco.com

Revision: 1.0
Revision Date: 23Mar26