i-STAT TBI Control Levels 1, 2

Intended for use with i-STAT Alinity Instrument (Model 500)

NAME

i-STAT TBI Control Level 1 (REF 06P17-25)

i-STAT TBI Control Level 2 (REF 06P17-26)

INTENDED USE

The i-STAT TBI Controls are available to monitor the performance of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) assays on the i-STAT Alinity Instrument.

REAGENTS

Contents: Each box contains 6 vials, each vial contains 1 mL of frozen serum.

Composition:

Ingredient Name	Qty (% by weight)
Human Source Material	30-60%
Buffers and Preservatives	40-70%
Glial fibrillary acidic protein (GFAP) Antigen	<0.01%
Ubiquitin carboxy-terminal hydrolase L1 (UCH-L1) Antigen	<0.01%

Warnings and Precautions

- For *in vitro* diagnostic use.
- Safety Data Sheets are available in the Support section of the website at www.globalpointofcare.abbott.
- Each plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found negative/non-reactive for the presence of hepatitis B, hepatitis C, and human immunodeficiency virus (HIV) 1 and 2. Because no known test method can offer complete assurance that infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.
- Do not use if arrived thawed or uncapped. Bacterial contamination can cause an increase in turbidity. Do not use the control if there is visible evidence of microbial growth or gross contamination.
- Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Storage Conditions

- Store frozen at ≤ -20 °C (-4°F) until the expiration date printed on the box and vial labels.
- Do not use beyond the expiration date.

INSTRUMENTS

The i-STAT TBI Controls levels 1 and 2 are intended for use with the i-STAT Alinity instrument. The i-STAT Alinity System should be used by healthcare professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

The i-STAT Alinity System incorporates a comprehensive group of components needed to perform sample analysis. A portable instrument and a cartridge with the required tests, using 2-3 drops of a sample will allow the operator to view the results.

For a detailed description of the instrument and system procedures, refer to the i-STAT Alinity System Operations Manual located at www.globalpointofcare.abbott.

PROCEDURE

Prerequisites

- Vials, cartridges, and instruments must be at the same temperature.
- **i-STAT TBI Control** vials should stand at room temperature (18 to 30°C or 64 to 86°F) for a minimum of 15 minutes, for thawing.

After thawing:

- Material may be stored capped at room temperature 18-30°C (64-86°F) or refrigerated 2-8°C (35-46°F) for up to 4 hours prior to testing.
- Do not refreeze.

Performing Quality Control Testing

1. Press **Power** and allow instrument to power on.

   Note: After powering on the instrument, one or more alert messages may display. Read the message carefully and perform the functions necessary to evaluate and/or clear the alert. The **Home** screen will display when the alerts have been successfully managed.

2. From the **Home** screen touch **More Options** > **Quality Options** > **Quality Control**. Three options are available. The default is **Perform Unscheduled QC**.
3. Touch the appropriate button and continue to follow the prompts on the screen.
   - The controls are housed in dropper vials to enable convenient transfer of the fluid from the vial into the cartridge.
   - **Before transferring** the fluid to the cartridge, **gently invert the vial a least 10 times to ensure homogeneity**.

   Note: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion.

   - Remove the cap and direct the dropper tip into the cartridge sample well. Fill the cartridge to the fill mark.
   - Close the cartridge.
   - When prompted insert the cartridge into the instrument's cartridge port.

ACCEPTABLE CRITERIA

Target Value

Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges and instruments that have passed the Electronic Simulator test are printed on a value assignment sheet and are also provided in an electronic file, electronic value assignment sheet (eVAS) posted on the APOC website at www.globalpointofcare.abbott.

Ranges

Refer to Value Assignment Sheet (VAS) or electronic version (eVAS) for the target (mean) the acceptable range and units of measurement for:

Assays	Unit
GFAP	pg/mL
UCH-L1	pg/mL

Limitation

Target values are specific to the i-STAT Alinity System. Results may differ if used with other methods.

If a result for a level is outside the range published in the Value Assignment Sheet, verify the following conditions are met and repeat the test.

- The correct expected values insert is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge pouch and control ampule or vial have not been exceeded.
- Room temperature expiration date for cartridge has not been exceeded.
- Cartridge and control have been stored correctly.
- The control has been handled correctly–see the directions for use.
- The instrument being used passes the Electronic Simulator test.

Note: Follow facility policy regarding control results that do not fall within assigned ranges.

METROLOGICAL TRACEABILITY

The i-STAT System test for glial fibrillary acidic protein (GFAP) or ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) measures GFAP and UCH-L1 amount-of-substance concentration in plasma (units of measure: pg/mL) for *in vitro* diagnostic use.

There are no internationally recognized standard reference materials available for either glial fibrillary acidic protein (GFAP) or ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1). GFAP and UCH-L1 values assigned to i-STAT controls and calibration verification materials are traceable to Abbott Point of Care's working calibrators prepared using recombinant GFAP and UCH-L1 (expressed and purified from *E. coli*). The working calibrators are traceable to an in-house Reference Standard prepared from recombinant GFAP and UCH-L1 (expressed and purified from *E. coli*).

i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

KEY TO SYMBOLS

Symbol	Definition/Use
	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used.
LOT	The Manufacturer lot number/batch will appear adjacent to this symbol
	Contains sufficient for <n> tests
EU REP	Authorized representative in the European Community
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
REF	Catalog number, list number, or reference
	Do not re-use. Do not refreeze.
	Manufacturer
	Consult instructions for use or see System Manual for instructions.
IVD	*In vitro* diagnostic medical device
CE 0344	A mark that indicates conformity to the legal requirements of the appropriate European Union (EU) Directive(s) and Regulation(s) with respect to safety, health, environment and consumer protection.
CONTROL	Control
	Biological Risks
HUMAN SERUM	Contains human serum
TBI	Traumatic Brain Injury
	Caution: Read all warnings and precautions in instructions for use

Symbol	Definition/Use
	Device for near-patient testing
	Importer in the European Community
	For use with i-STAT Alinity System only

ADDITIONAL INFORMATION

To obtain additional product information and technical support, refer to the Abbott company website at www.globalpointofcare.abbott.

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

Technical Support: please contact your local service provider for service information.

For customers in the European Union: A summary of safety and performance (SSP) for this device is available at https://ec.europa.eu/tools/eudamed/ after the launch of the European Database on Medical Devices. Search for the device using the UDI-DI provided on the outer packaging of the device. A copy of the SSP can also be requested from the European Authorized Representative or the manufacturer.