

HD Chip

FOR RESEARCH USE ONLY – NOT FOR USE IN DIAGNOSTIC PROCEDURES

SUMMARY AND TEST PRINCIPLE:

Collagen and tissue thromboplastin are coated inside the microchip capillary of HD Chip, and it allows analysis of white thrombus formation, the mixture of the activated platelets and fibrin. HD Chip enables you to analyze the function of platelets and blood aggregation under physiologic blood flow conditions.

REAGENTS AND MATERIALS PROVIDED:

Item	Contents	Catalog Number
HD Chip	20 chips	19002

MATERIALS REQUIRED BUT NOT PROVIDED:

Item	Catalog Number
T-TAS 01 Total Thrombus Formation Analysis System Instrument	18001
AR Chip & HD Chip Reservoir set	19003
CaCTI Reagent	19004
BD Vacutainer® Citrate tubes (BD Life Sciences Product Catalog number 368273)	N/A
Mineral Oil (Sigma-Aldrich catalog number 330779)	N/A
Pipettor capable of pipetting 450-480 µL and disposable pipette tips	N/A
Pipettor capable of pipetting 20 µL and disposable pipette tips	N/A
Microtubes (1-2 ml tubes are recommended)	N/A
Kimwipes or other dust-free tissue	N/A

WARNINGS AND PRECAUTIONS:

- For research use only.
- Blood specimens, used assay chips, used reservoirs, and pipette tips are potentially infectious. Proper handling and disposal methods should be followed in accordance with local, state and federal regulations.
- Results should be interpreted in conjunction with other research findings and test results from research facilities.
- Carefully follow the instructions and procedures described in this package insert.
- Do not use products beyond the expiration date printed on the label.
- Do not use the HD chip if the protective pouch is torn or punctured prior to opening.
- Do not use chips that are bent or deformed.

STORAGE AND HANDLING REQUIREMENTS:

Do not remove the assay chip from the pouch until ready for use.

The unopened assay chip is stable when stored at 2-8 °C until the expiration date on the package label. Assay chips must be used as soon as possible after removal from the sealed pouch.

Before using refrigerated assay chips, allow individual pouched assay chips to reach room temperature for at least 30 minutes before use. If a kit box containing multiple assay chips is being removed from refrigeration, allow the box to reach room temperature for at least 1 hour before use.

SPECIMEN COLLECTION AND PREPARATION:

Measurements with the T-TAS 01 system involve assessment of biological activity and is dependent on proper collection of blood specimens. Blood specimens collected for analysis with the HD chip should be collected using BD Vacutainer® Citrate tubes (BD Life Sciences Product Catalog number 368273). Other anticoagulants are not suitable for use with the HD assay and should be avoided.

- Collect fresh venous whole blood that has been anticoagulated with 3.2 % sodium citrate using a collection needle at least 21 gauge (18 ~ 21 gauge) in diameter.
- Mix the anticoagulant with the sample by gently inverting the tube 5 times.
- Store the blood sample upright at room temperature for at least 30 minutes prior to testing with the HD chip. Do not use a rocker platform.
- Blood samples should be measured between 30 minutes to 3 hours after collection.
- Transport specimens upright at room temperature and avoid extreme temperatures. Use of pneumatic tube transport systems may cause platelet activation. Such transport systems will need to be validated by the laboratory for suitability.
- Avoid using hemolyzed specimens. If a specimen appears to be hemolyzed, another specimen should be obtained and tested.
- If the test needs to be repeated, ensure that the blood sample has been maintained according to the conditions described above, or collect a new sample.

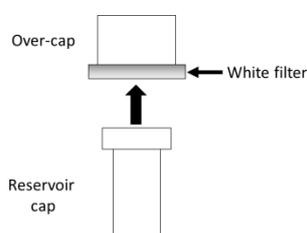
TEST PROCEDURE:

Procedural Notes:

- Do not remove the assay chip from the pouch until ready for use.
- Ensure that assay chips have reached room temperature prior to performing the assay.
- Assemble reservoir cap and over-cap.
- Care should be taken to avoid air gaps and bubbles. Blood samples should be carefully dispensed down the wall of the reservoir to avoid introducing bubbles.
- It is important to ensure a tight connection between the reservoir and nozzle, and between the reservoir cap and reservoir. A loose connection may be compressed when attaching the reservoir to the assay chip sample port, which may cause the blood sample to enter the analytical path prematurely. If the blood sample enters the analytical path before the assay is started, it is recommended to cancel the assay and repeat the procedure using another assay chip.
- The reservoir should be inserted into the assay chip sample port vertically. Avoid holding the nozzle during this step and avoid connecting the reservoir to the assay chip sample port at an angle.

Assay Preparation:

- Do not remove the assay chip from the pouch until ready for use.
- Assay chips may be placed on the pre-heater for at least 1 min before the assay, to allow stabilization of the temperature. This step is optional, but can reduce the time required to heat the chip to the operating temperature.
- Assemble the reservoir cap and over-cap prior to performing the assay by firmly pressing the wide part of the reservoir cap to the white filter on the over-cap.



Testing Blood Samples:

The HD assay is performed at 37 °C, which is controlled by a heated stage on the instrument. The T-TAS 01 assay procedure is summarized below, and the user is guided through each of the steps via on-screen instructions.

1. Remove the assay chip from the sealed pouch and insert the assay chip into the stage on the T-TAS 01 instrument.
2. Wipe any excess mineral oil from the nozzle using a Kimwipe or dust-free tissue and connect the reservoir to the nozzle firmly.
3. Dispense 20 μL of CaCTI in a microtube.
4. Mix the blood sample by gently inverting 3 times, dispense 480 μL in the microtube with CaCTI, and mix by pipetting without creating bubbles.
(Carry out the following operations quickly as coagulation reaction starts at this point)
5. Pipette 450 μL of the mixed blood sample into the reservoir. The allowable pipette volume can be between 440-460 μL .
6. While holding the reservoir, insert the reservoir cap firmly with a slight twisting motion, and then lift to remove its over-cap.
7. While holding the reservoir, invert the reservoir and connect it vertically to the sample port on the assay chip with a slight twisting motion until resistance is felt. Avoid making the connection at an angle.
8. Push the start button on the computer touchscreen. Results are generated automatically.

After the assay has been completed, gently remove the reservoir from the sample port on the assay chip. Hold the reservoir horizontally to avoid leakage of its contents, and twist to remove the used reservoir from the nozzle. Place the nozzle in its holder and discard used reservoirs, pipette tips, and assay chips in a suitable biohazard waste container.

RESULTS:

Results are expressed as AUC, which is the area under the flow pressure curve over a 30 minute period.

ASSISTANCE:

For assistance, please contact your local distributor.

DEFINITION OF SYMBOLS:

Symbol	Definition
	Do Not Re-use
 YYYY-MM-DD	Use-by date
	Consult Instructions for use
	Batch code
	Catalog number
	Temperature limit
	Manufacturer
	Number of contents
	Do not use if package is damaged



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