

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k111762

**B. Purpose for Submission:**

New device

**C. Measurand:**

Calibrator Set for ST AIA-PACK DHEA-S assay

**D. Type of Test:**

Calibration materials

**E. Applicant:**

Tosoh Bioscience, Inc.

**F. Proprietary and Established Names:**

ST AIA-PACK DHEA-S Calibrator Set

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
JIT	Class II	21 CFR 862.1150 Calibrator	Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

Refer to indication for use below.

2. Indication(s) for use:

The ST AIA-PACK DHEA-S CALIBRATOR SET is intended for IN VITRO DIAGNOSTIC USE ONLY for the calibration of the ST AIA-PACK DHEA-S assay.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Tosoh AIA System analyzers

**I. Device Description:**

The ST AIA-PACK DHEA-S CALIBRATOR SET contains ready to use human sera (sodium azide as a preservative) with assigned levels of DHEA-S. Calibration should be performed according to the schedule indicated in the TOSOH AIA System Operator's Manual.

The sponsor declared in the labeling that the material derived from human origin used in the preparations of these calibrators has been tested by FDA-cleared methods and found negative for the presence of HBsAg and antibody to HIV-1 and HCV.

Kit content and target values:

Level	Target Value (µg/dL)	Volume Provided
CALIBRATOR (1)	0	2x 1 mL
CALIBRATOR (2)	5.0	2x 1 mL
CALIBRATOR (3)	12	2x 1 mL
CALIBRATOR (4)	60	2x 1 mL
CALIBRATOR (5)	300	2x 1 mL
CALIBRATOR (6)	1200	2x 1 mL

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Access® DHEA-S Calibrators

2. Predicate 510(k) number(s):

k040181

3. Comparison with predicate:

Characteristic	Tosoh ST AIA-PACK DHEA-S Calibrator Set (New Device)	Access® DHEA-S Calibrators (Predicate Device)
Similarities		
Intended Use/ Indications for use	Same	For use in the calibration of DHEA-S assay on the indicated analyzers.
Format	Same	Ready to use liquid calibrators

Levels	Same	6
Shelf-life Stability	Same	12 months at 2-8°C
Differences		
Matrix	Human serum	Bovine serum / buffer base with surfactant and preservative
Calibration Stability	Up to 90 days	28 days
Open Vial Stability	2-8°C, 1 day	2-10 °C, 28 days
Target Values	0, 5, 12, 60, 300 and 1200 µg/dL	0, 20, 50, 200, 500 and 1000 µg/dL

**K. Standard/Guidance Document Referenced (if applicable):**

None were referenced.

**L. Test Principle:**

Not applicable

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

Not applicable

*b. Linearity/assay reportable range:*

Not applicable

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability

The assayed value of each calibrator level was standardized against reference calibrators. The reference calibrators were prepared by weighing dehydroisoandrosterone 3-sulfate sodium salt dihydrate (DHEA) from a commercial vendor into an analyte-free human serum matrix.

Value Assignment:

For each calibrator set lot manufactured, the calibrators are assayed in 5 replicates each on two AIA-1800 analyzers using 3 lots of reagent. The instruments were calibrated using the reference calibrators. The assigned value of each calibrator is the grand mean of 30 determinations of the respective calibrator level.

Stability:

Real time testing was performed at one site using one AIA-1800 analyzer. The stability protocol and the acceptance criteria have been reviewed and found to be acceptable.

- Shelf-life stability:  
Real time testing result support the package insert claim of 12 months at 2-8°C.
- Open-vial stability:  
Real time testing result support the package insert claim that the calibrator set is stable for one day after it had been opened, sealed and stored at 2-8°C.
- Calibration stability:  
Real time testing results support the package insert claim of 90 days from the date of calibration.

*d. Detection limit:*

Not applicable

*e. Analytical specificity:*

Not applicable

*f. Assay cut-off:*

Not applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

Not applicable

*b. Matrix comparison:*

Not applicable

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable

*b. Clinical specificity:*

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.