

# TECOmedical Group Human Sclerostin HS EIA Kit

*always your partner*

An immunocapture enzyme assay for the determination of sclerostin in human serum and plasma

For Research Use Only.  
Not for Use in Diagnostic Procedures.



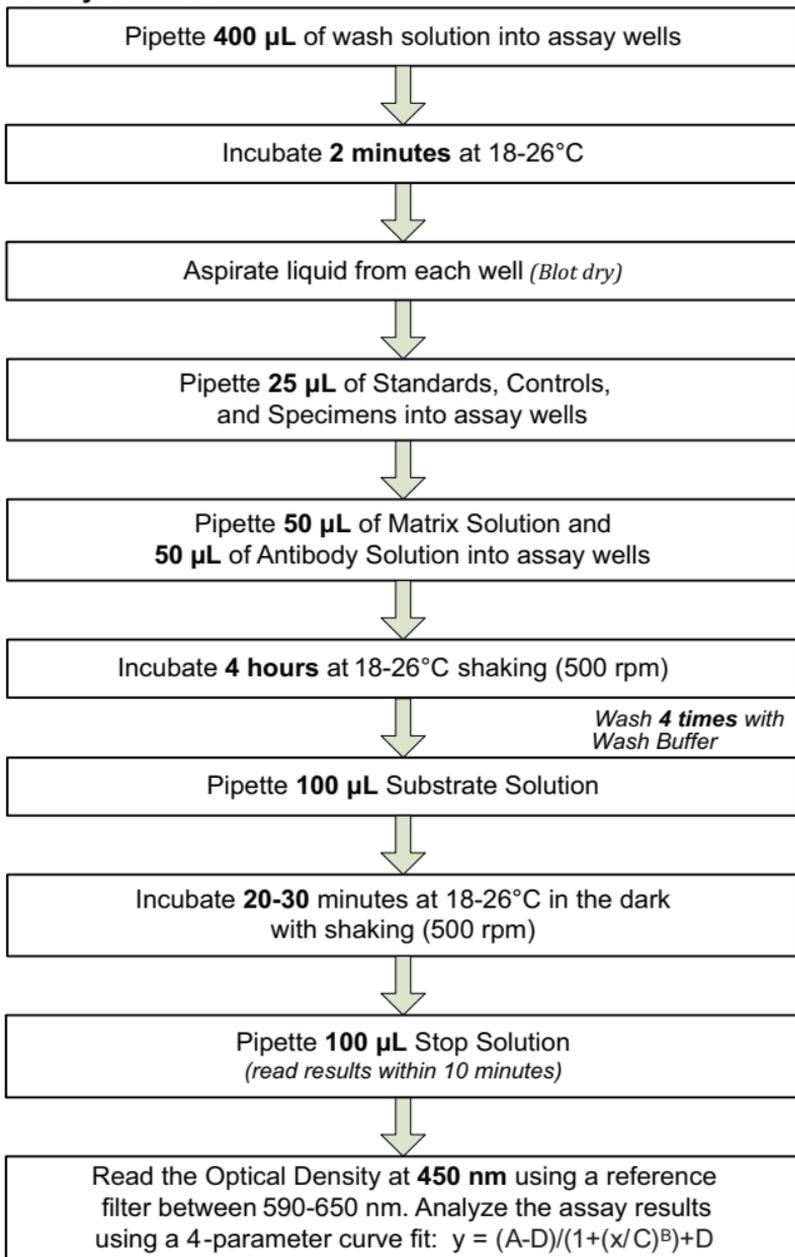
REF TE1023HS

# TECOmedical Sclerostin HS EIA Summary

## Reagent, Standards, Controls, and Sample Preparation

- Dilute Wash Buffer Concentrate **1:20** with DI Water.

## Assay Procedure



## SUMMARY AND EXPLANATION

The Human Sclerostin High Sensitivity (HS) Enzyme Immunoassay is a 96-well, direct-capture immunoassay for the measurement of Sclerostin in human serum, plasma and cell culture (osteocytes and chondrocytes). Sclerostin is the protein product of the SOST gene, which is located at 17q12-21 and highly conserved across vertebrate species. The highest expression of sclerostin throughout the adult skeleton has been observed in hypertrophic chondrocytes and osteocytes. Sclerostin blocks canonical Wnt signaling by binding to the Wnt coreceptors LRP5/6, inhibiting bone formation by regulating osteoblast function and promoting osteoblast apoptosis.<sup>1-3</sup> Sclerostin also antagonizes bone morphogenetic protein (BMP) action (e.g. osteoblast differentiation), but does not inhibit direct BMP-induced responses.<sup>4-7</sup> Sclerostin expression is down-regulated by Parathyroid hormone (PTH), as well as, by the mechanical stimulation of bone.<sup>8-12</sup> Reduced expression of sclerostin can result in van Buchem disease, while a complete absence results in Sclerosteosis. Patients affected by Sclerosteosis show progressive hyperostosis and sclerosis of the skull, mandible and all long bones. Bone mineral density (BMD), bone volume, bone formation rate, and bone strength are significantly increased, while overall skeletal morphology appears to be normal.<sup>13-14</sup> A predominance of sclerostin causes reduced bone quality (Osteoporosis pseudoglioma (OPPG) syndrome). Down-regulation of sclerostin might be used as a treatment for diseases such as osteoporosis, promote osseointegration of implants, prevent periprosthetic bone loss, or treat non-union in fractures.<sup>15-20</sup> Local enhancement of sclerostin expression might be used to prevent cancer metastasis and minimize further expansion of ectopic bone formation.<sup>21</sup>

## PRINCIPLE OF THE PROCEDURE

The Human Sclerostin HS Enzyme Immunoassay for the quantitation of Sclerostin in human plasma and serum is a two-step procedure utilizing (1) a microassay plate coated with streptavidin and a biotinylated goat polyclonal antibody that binds specifically to human Sclerostin, (2) a HRP-conjugated monoclonal anti-human Sclerostin antibody, and (3) a chromogenic substrate.

Prior to Step 1, The microassay plate is pre-washed for 2 minutes, the wash buffer aspirated and the remaining liquid removed by tapping on absorbent paper.

In Step 1, Standards, Controls, and test specimens are added to microassay wells pre-coated with streptavidin. Biotin-conjugated primary polyclonal anti-human Sclerostin antibody and horseradish peroxidase (HRP)-conjugated secondary monoclonal anti-human Sclerostin antibody is added to each test well. Sclerostin present in the Standards, Controls or specimens are captured in the microassay wells through binding of the biotinylated primary antibody to the streptavidin immobilized on the plate and simultaneously detected by the HRP-conjugated secondary antibody. After a 4 hour incubation, a wash cycle removes unbound material.

In Step 2, a chromogenic enzyme substrate is added to each microassay well. The bound HRP-conjugate reacts with the substrate, forming a blue color. After incubation the enzyme reaction is stopped chemically, the color changes to yellow, and the color intensity is measured spectrophotometrically at 450 nm with a 590-650 nm reference filter. The color intensity of the reaction mixture is proportional to the concentration of Sclerostin present in the test specimens, Standards, and Controls.

## REAGENTS AND MATERIALS PROVIDED

### 96 Assays for Human Sclerostin

Human Sclerostin HS Enzyme Immunoassay kit contains the following:

<b>A Sclerostin Standards</b>	<b>Parts 5178 – 5183</b>	<b>0.5 mL each</b>
Concentration: 0, 0.05, 0.2, 0.5, 1.5, 3 ng/mL (0, 2.2, 8.8, 22, 66, 132 pmol/L)		
<b>F</b>	Ready to use. Each contains recombinant protein with assigned Sclerostin concentration (ng/mL) based on amino acid analysis, protein stabilizers, 0.06% BND, 0.05% Tween-20®	
<b>L Sclerostin Low Control</b>	<b>Part 5184</b>	<b>0.5 mL</b>
Ready to use. Contains recombinant protein with assigned Sclerostin concentration (ng/mL), protein stabilizers, 0.06% BND, 0.05% Tween-20®		
<b>H Sclerostin High Control</b>	<b>Part 5185</b>	<b>0.5 mL</b>
Ready to use. Contains recombinant protein with assigned Sclerostin concentration (ng/mL), protein stabilizers, 0.06% BND, 0.05% Tween-20®		
<b>1 Microassay Plate</b>	<b>Part 4634</b>	<b>12 x 8 wells</b>
Eight-well strips coated with Streptavidin in a resealable foil pouch		
<b>2 Stop Solution</b>	<b>Part A9947</b>	<b>12 mL</b>
Contains 1M (4%) Hydrochloric Acid		
<b>3 20X Wash Buffer Concentrate</b>	<b>Part A9957</b>	<b>50 mL</b>
Contains phosphate buffered saline (PBS), 1.0% Tween-20® and 0.035% Proclin® 300		
<b>4 Sample Diluent</b>	<b>Part 5186</b>	<b>5 mL</b>
Contains protein stabilizers, 0.06% BND, 0.05% Tween-20®		
<b>5 Matrix Solution</b>	<b>Part 5188</b>	<b>7 mL</b>
Contains protein stabilizers, 0.12% BND		
<b>6 Sclerostin Antibody Solution</b>	<b>Part 5191</b>	<b>7 mL</b>
Ready to use. Contains biotin-conjugated polyclonal anti-human Sclerostin antibody and horseradish peroxidase-conjugated monoclonal anti-human Sclerostin antibody, protein stabilizers, 0.06% BND, 0.05% Tween-20®		
<b>7 TMB Substrate</b>	<b>Part 5190</b>	<b>12 mL</b>
Ready to use. Contains 3,3',5,5'-tetramethylbenzidine (TMB) and Hydrogen Peroxide (H <sub>2</sub> O <sub>2</sub> )		
Tween-20® is a registered trademark of ICI Americas Inc.		
ProCin® is a registered trademark of Rohm and Haas Company.		

## **MATERIALS REQUIRED BUT NOT PROVIDED**

- Timer (60 minute range)
- Container and graduated cylinder for wash buffer dilution
- Wash bottle or other validated immunoassay washing system
- Micropipettes and disposable pipette tips
- Adjustable multichannel pipette (8 or 12 channels) or repeating micropipettes
- Reagent reservoirs for adding conjugate, substrate and stop solutions to plate (use clean, unused reservoirs for each reagent)
- Plate reader capable of  $A_{450}$  readings from 0.0 to at least 3.0 (Reference filter 590-650 nm)
- Deionized or distilled water
- Vortex mixer
- ELISA plate shaker (orbital shaker; 500 rpm)

## **WARNINGS AND PRECAUTIONS**

1. *For Research Use Only. Not for use in diagnostic procedures.*
2. Treat specimen samples as potentially biohazardous material. Follow Universal Precautions when handling contents of this kit and any patient samples. Since no test method can offer complete assurance that infectious agents are absent, these materials should be handled at Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories,"<sup>22-23</sup>
3. Material of animal origin used in the preparation of this kit has been obtained from animals certified as healthy, but these materials should be handled as potentially infectious.
4. Wear suitable protective clothing, gloves, and eye/face protection when handling contents of this kit.
5. Use the supplied reagents as an integral unit prior to the expiration date indicated on the package label.
6. Store assay reagents as indicated.
7. Do not use Coated Strips if pouch is punctured.
8. ProClin® 300 is used as a preservative. Incidental contact with or ingestion of buffers or reagents containing ProClin® can cause irritation to the skin, eyes, or mouth. Use good laboratory practices to reduce exposure. Seek medical attention if symptoms are experienced.
9. The Stop Solution is considered corrosive and can cause irritation. Do not ingest. Avoid contact with eyes, skin, and clothing. If contact is made, immediately rinse affected area with water. If ingested, call a physician.
10. Use of multichannel pipettes or repeat pipettors is recommended to ensure timely delivery of reagents.
11. For accurate measurement of samples, add samples and standards precisely. Pipette carefully using only calibrated equipment.

12. Proper collection and storage of test specimens are essential for accurate results (see *SPECIMEN HANDLING AND PREPARATION*).
13. Avoid microbial or cross-contamination of specimens or reagents.
14. Test each sample in duplicate.
15. Do not use any single microassay well for more than one test.
16. Using incubation times and temperatures other than those indicated in the Procedure section may give erroneous results.
17. The TMB Substrate must be protected from light and contact with metal or rubber during storage and incubation. Avoid contact with eyes, skin, and clothing. If contact is made, immediately rinse affected area with water.
18. Do not allow microassay wells to dry once the assay has begun.
19. When removing liquid from the microassay wells, do not scrape or touch the bottom of the wells.
20. Hyperlipemic or contaminated specimens may give erroneous results.
21. To avoid aerosol formation during washing, use an apparatus to aspirate the wash fluid into a bottle containing household bleach.
22. A wash bottle or automated filling device should be used to wash the plate (*ASSAY PROCEDURE, step 7*). For best results, do not use a multichannel pipette to wash the microassay plate.
23. Dispose of containers and unused contents in accordance with Federal, State, and Local regulations.
24. For more information, consult Safety Data Sheet available on [quidel.com](http://quidel.com).

## **STORAGE**

Store the unopened kit and unused kit components at 2-8°C.

## **INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS**

Cloudiness or discoloration of the diluted Wash Buffer indicates a deterioration of this reagent. If either of these conditions occur, the solution should be discarded.

## **REAGENT PREPARATION**

**Bring all reagents and materials to 18–26°C before use.**

After removing the needed reagents and materials, return the unused items to their appropriate storage temperatures (see *STORAGE*).

### **Microassay Strips**

Determine the number of strips needed for the assay. Assay the Standards, Controls and Samples as quickly as possible (< 15 minutes) and, respectively, in the same order in duplicate. Remove the unneeded strips, place them in the storage bag, reseal the bag, and return it to 2-8°C. Secure the strips to be used in the assay in the assay plate frame.

## **Wash Buffer**

Mix the 20X Wash Buffer Concentrate by inverting the bottle several times. If the 20X Wash Buffer Concentrate has been stored at 2-8°C, crystals may have formed. To dissolve the crystals, warm the bottle in a 37-50°C water bath until all crystals have dissolved, and follow by mixing thoroughly. Prepare the Wash Buffer by diluting the entire contents of the bottle of 20X Wash Buffer concentrate up to one liter with distilled or deionized water. Mix thoroughly. The Wash Buffer is stable for 30 days when stored in a clean container at 2-8°C. If discoloration or cloudiness occurs, discard the reagent.

## **Standards and Controls**

Standards and Controls are supplied ready to use and do not require dilution or preparation prior to use.

## **SPECIMEN HANDLING AND PREPARATION**

**Handle and dispose of all specimens using Universal Precautions.**

### **Specimen Collection and Storage**

Plasma (Heparin and EDTA) and serum have been used as samples in the Human Sclerostin HS Assay. Collect specimens using standard venipuncture techniques. Specimens should be collected in such a way to avoid hemolysis. For serum specimens, allow the blood to clot, and separate the serum by centrifugation. Both Heparin and EDTA plasma can be used. See OBSERVED VALUES section for more information.

### **Stability of Samples**

Samples can be stored for 3 days at room temperature, 5 days at 2-8°C, at ≤ -20°C for 24 months and at ≤ -80°C for > 24 months. Up to three thaw cycles may be performed without affecting the samples. If samples need additional freezing for further analysis, We suggest freezing multiple aliquots of the specimen to prevent exceeding the recommended number of freeze/thaw cycles.

**CAUTION: Treat all specimens as potentially infectious. Use Universal Precautions. Do not use contaminated or improperly stored specimens.**

**Normal Specimens must not be diluted. Observed values should be above the LLOQ and not exceed the ULOQ.**

**Specimens with high levels of sclerostin (above the standard curve) may require dilution with Sample Diluent and retesting.**

## **ASSAY PROCEDURE**

**Read entire product insert before beginning the assay.**

See *REAGENT PREPARATION* and *WARNINGS AND PRECAUTIONS*.

1. Record the microassay well positions corresponding to all test samples, Standards, and Controls, as well as the indicated lot numbers from the vial labels. Label one corner of the Microassay Plate for orientation.

2. Prepare the microassay strips as follows:
  - a. Using a wash bottle or automated plate washing device, add approximately 400  $\mu\text{L}$  Wash Buffer to each well.
  - b. Incubate the wells for two minutes at 18-26°C.
  - c. Aspirate the contents from each well.
  - d. Invert the plate and tap firmly on absorbent paper to remove any remaining liquid.
3. Add 25  $\mu\text{L}$  Standards, Controls, or specimens to the assigned duplicate wells.
4. Add 50  $\mu\text{L}$  Matrix Solution to each well. Use of a multichannel pipette is recommended.
5. Add 50  $\mu\text{L}$  Antibody Solution to each well. The entire plate must be loaded within 15 minutes of loading the first sample onto the plate. Use of a multichannel pipette is recommended.
6. Cover the wells with sealing tape, and incubate for 4 hours at 18-26°C with shaking (500 rpm).
7. Wash the microassay wells a total of 4 times using the following procedure:
  - a. Aspirate the contents from each well.
  - b. Using a wash bottle or automated plate washing device, add approximately 400  $\mu\text{L}$  diluted Wash Buffer to each well.  
**NOTE:** Use of an automatic plate washer is recommended. The washer should be primed with Wash Buffer immediately before beginning wash procedure. **DO NOT** use a multichannel pipette for washing.
  - c. Immediately aspirate the contents from each well.
  - d. Invert the plate, and tap firmly on absorbent paper to remove any remaining liquid.
  - e. **Repeat steps b-d three additional times for a total of four washes.**
  - f. After the fourth wash cycle, invert the plate and tap firmly on absorbent paper to remove any remaining liquid.
8. Immediately following the wash procedure, dispense 100  $\mu\text{L}$  of the TMB Substrate Solution into each well. Use of a multichannel pipette is recommended.
9. Incubate the microassay strips at 18-26°C in the dark for 20-30 minutes with shaking (500 rpm).
10. Add 100  $\mu\text{L}$  of Stop Solution to each well to stop the enzymatic reaction. The Stop Solution should be added to the wells in the same order and at the same rate that the Substrate Solution had been added. Use of a multichannel pipette is recommended.
11. Gently tap the plate on the bench top to disperse the color development completely and evenly.  
**NOTE: Optimal results may be obtained by using the plate reader's auto-mix function (if available) just prior to reading the plate.**
12. Determine the absorbance reading at 450 nm (using a reference filter between 590-650 nm) for each test well within 10 minutes after the addition of the Stop Solution (step 11).

13. Determine the concentration of Samples and Controls from the standard curve.
14. Dispose of the remaining specimens and controls and the used microassay strips (see *WARNINGS AND PRECAUTIONS*).

## QUALITY CONTROL

The Certificate of Analysis included in this kit is lot specific and is to be used to verify that the results obtained by your laboratory are similar to those obtained at Quidel Corporation. The optical density values provided are intended as a guideline only. The results obtained by your laboratory may differ.

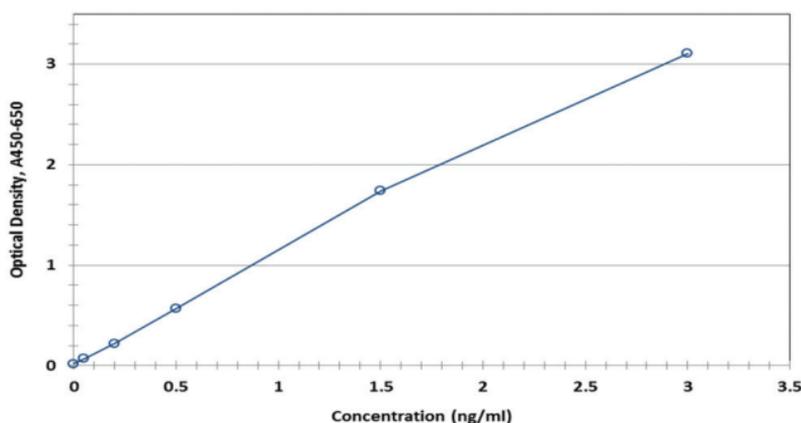
Quality control ranges are provided. The control values are intended to verify the validity of the curve and sample results. Each laboratory should establish its own parameters for acceptable assay limits. If the control values are NOT within your laboratory's acceptance limits, the assay results should be considered questionable, and the samples should be repeated.

## INTERPRETATION OF RESULTS

### Use of the Standard Curve

The standard curve for the Sclerostin HS EIA is generated using the  $A_{450-650}$  values for each Standard (on the y axis) and the assigned concentration for each Sclerostin Standard (on the x axis). After 4-parameter regression, the generated standard curve must meet the validation requirements (see below). Most plate-reading software and computers are capable of performing these calculations.

**Figure 1: Representative Standard Curve**



Sample	$A_{450-650}$	ng/mL
Standard A	0.021	0
Standard B	0.072	0.05
Standard C	0.221	0.20
Standard D	0.568	0.50
Standard E	1.742	1.50
Standard F	3.108	3.00

## Calculation of Actual Sclerostin Concentration in Test Specimens

The actual Sclerostin concentration present in each undiluted test specimen is determined from the Kit Standard Curve.

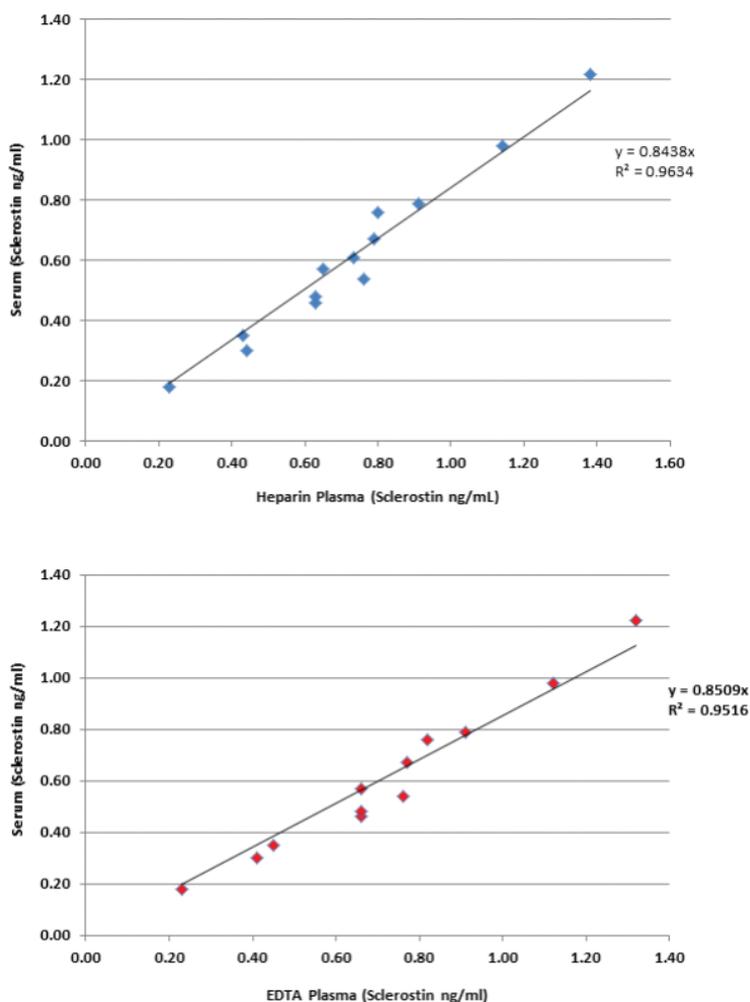
### OBSERVED VALUES

Serum from normal donors were tested in the Human Sclerostin HS Enzyme Immunoassay kit. The results are presented below.

Group	n	Mean (ng/mL)	SD (ng/mL)
Premenopausal women	24	0.45	0.15
Postmenopausal women	20	0.51	0.14
Men	11	0.59	0.13

**NOTE:** The mean and Standard Deviation (SD) behavior of sclerostin concentrations determined for serum samples may vary between laboratories. Therefore, it is recommended that each laboratory determine the mean sclerostin concentration and standard deviation values for samples.

**Figure 2: Sclerostin Values**



Sample	n	Mean (ng/mL)	SD (ng/mL)
Serum	9	1.15	0.78
Heparin plasma	9	1.34	0.88
EDTA plasma	9	1.37	0.90

**NOTE:** 20% higher Sclerostin values have been observed in Heparin and EDTA plasma, compared with serum.

## PERFORMANCE OF THE TEST

### Limits (as determined by Point-to-Point for LOD and LLOQ)

**LOD:** The limit of detection (LOD) for the Sclerostin HS EIA is 0.009 ng/mL, determined by the upper 3SD limit in a zero standard study.

**LLOQ:** The lower limit of quantitation (LLOQ) for the Sclerostin HS EIA is 0.058 ng/mL, the lowest concentration on the standard curve that met CLSI criteria for accuracy and precision.

**ULOQ:** The upper limit of quantitation (ULOQ) for the Sclerostin HS EIA is 3.5 ng/mL, the highest concentration that met CLSI criteria for accuracy and precision.

### Interfering Substances

The following substances were tested in the Sclerostin HS EIA and found to not interfere with the assay using serum samples:

Substance	Concentration
Bilirubin	40 mg/dL
Hemoglobin	500 mg/dL
Triglycerides	3000 mg/dL
Glucose	1200 mg/dL
Cholesterol	500 mg/dL
Albumin	6000 mg/dL
Gamma Globulin	6000 mg/dL

### Precision

Intra- and inter-assay precision was determined by assaying 20 replicates of 4 serum sample in 10 different assays.

Sample	Sclerostin (ng/mL)	Within-run <sup>1</sup> C.V. (%)	Between-run <sup>2</sup> C.V. (%)
Serum 1	0.67	4.0	4.8
Serum 2	1.80	4.2	4.4
Serum 3	2.44	3.9	4.3
Serum 4	1.12	3.7	4.5

<sup>1</sup>n = 20 replicates    <sup>2</sup>n = 10 runs

## Linearity

Linearity was performed by diluting samples with specimen diluent and comparing observed values with expected values. Typical results are provided below.

Sample	Dilution Factor	Observed Sclerostin (ng/mL) <sup>3</sup>	Expected Sclerostin (ng/mL) <sup>3</sup>	Recovery (%)
Serum 1	1	1.80	*	*
	2	0.88	0.90	98
	4	0.44	0.45	98
	8	0.22	0.23	100
Serum 2	1	2.34	*	*
	2	1.11	1.17	95
	4	0.56	0.59	96
	8	0.30	0.29	103
Serum 3	1	1.09	*	*
	2	0.54	0.55	99
	4	0.29	0.27	106
	8	0.15	0.14	108

<sup>3</sup>Dilution factor not included.

\*Intentionally left blank.

## Spike Recovery

Spike Recovery was performed by spiking samples with a known quantity of purified Sclerostin and comparing observed values with expected values.

Sample	Sclerostin (ng/mL)	Spike (ng/mL)	Result (ng/mL)	Recovery (%)
Serum 1	0.59	1.12	1.63	96
Serum 2	2.50	1.12	3.47	96
Serum 3	1.12	1.12	2.27	102

## Species Cross-reactivity

No cross-reaction with other species.

## ASSISTANCE

To place an order or for technical assistance, please contact a Quidel Representative at 800.874.1517, Monday through Friday, between 8:00 a.m. and 5:00 p.m., Eastern Time. Orders may also be placed by e-mail at [custserv@quidel.com](mailto:custserv@quidel.com) or by fax at 740.592.9820. For services outside the U.S., please contact your local distributor.

Additional information about Quidel and Quidel's products and distributors can be found on our website at [quidel.com](http://quidel.com).

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Sclerostin HS EIA

REF

Catalog Number



Manufacturer



Temperature Limitation



Biological risks

RUO

Research Use Only



Consult Instructions for Use



Contains sufficient for <n> tests

CONT

Contents / contains

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REF

TE1023HS – TECOmedical Sclerostin HS Enzyme Immunoassay Kit

Manufactured by



Quidel Corporation | 2005 E. State St. Suite 100  
Athens, OH 45701 USA | [quidel.com/spg](http://quidel.com/spg)

For

**TECO**medical Group



QUIDEL

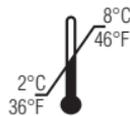
PIT102300EN01 (08/16)

# TECOmedical Group Human Sclerostin HS EIA Kit

*always your partner*

An immunocapture enzyme assay for the determination of sclerostin in human serum and plasma

For Research Use Only.  
Not for Use in Diagnostic Procedures.



REF TE1023HS