

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 3 (human) Kit
Kit Catalog Numbers: K15189D-Series
Kit Lot Number: K0040459
Expiration Date: 31 Jan 2021

Acceptance Data/ Percent Recovery Specifications:

| Spot | Name | Calibrator | | KIP-3 Control 1 | | KIP-3 Control 2 | |
|------|--------------|------------|-------|-----------------|--------|-----------------|--------|
| | | Recovery | CV | Recovery | CV | Recovery | CV |
| 1 | αGST | 80% - 120% | < 20% | 75% - 125%* | < 20%* | 75% - 125%* | < 20%* |
| 2 | Calbindin | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 3 | Clusterin | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 4 | KIM-1 | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 5 | Osteoactivin | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 6 | TFF3 | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 7 | VEGF | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |

* See Additional Comments.

Acceptance Data/ Non Specific Binding Specifications:

| Spot | Name | NSB Spec |
|------|--------------|----------|
| 1 | αGST | < 1.0% |
| 2 | Calbindin | < 1.0% |
| 3 | Clusterin | < 1.0% |
| 4 | KIM-1 | < 1.0% |
| 5 | Osteoactivin | < 1.0% |
| 6 | TFF3 | < 1.0% |
| 7 | VEGF | < 1.0% |

Stock Concentration of Material Tested :

| Spot | Name | Item | Conc | Units |
|------|-----------|-----------------|--------|-------|
| 1 | αGST | 20X Calibrator | 40000 | pg/mL |
| | | KIP-3 Control 1 | 8690 | pg/mL |
| | | KIP-3 Control 2 | 463 | pg/mL |
| 2 | Calbindin | 20X Calibrator | 644000 | pg/mL |

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| | | | | |
|---|--------------|-----------------|---------|-------|
| | | KIP-3 Control 1 | 93700 | pg/mL |
| | | KIP-3 Control 2 | 5810 | pg/mL |
| 3 | Clusterin | 20X Calibrator | 4960000 | pg/mL |
| | | KIP-3 Control 1 | 696000 | pg/mL |
| | | KIP-3 Control 2 | 45200 | pg/mL |
| 4 | KIM-1 | 20X Calibrator | 530000 | pg/mL |
| | | KIP-3 Control 1 | 73200 | pg/mL |
| | | KIP-3 Control 2 | 4570 | pg/mL |
| 5 | Osteoactivin | 20X Calibrator | 956000 | pg/mL |
| | | KIP-3 Control 1 | 142000 | pg/mL |
| | | KIP-3 Control 2 | 9810 | pg/mL |
| 6 | TFF3 | 20X Calibrator | 48000 | pg/mL |
| | | KIP-3 Control 1 | 6250 | pg/mL |
| | | KIP-3 Control 2 | 464 | pg/mL |
| 7 | VEGF | 20X Calibrator | 56600 | pg/mL |
| | | KIP-3 Control 1 | 8690 | pg/mL |
| | | KIP-3 Control 2 | 599 | pg/mL |

Control data was generated utilizing internal reference controls.

Concentrations provided in this table refer to the stock concentration of the calibrators. For top of the standard curve concentrations, please refer to the Standard Curve Data

Standard Curve Data:

| αGST - Spot 1 | | | Calbindin - Spot 2 | | | Clusterin - Spot 3 | | |
|---------------|------------|-----|--------------------|------------|-----|--------------------|------------|-----|
| Conc. pg/mL | ECL Signal | %CV | Conc. pg/mL | ECL Signal | %CV | Conc. pg/mL | ECL Signal | %CV |
| 2000 | 73,500 | 6.8 | 32200 | 1,140,000 | 5.1 | 248000 | 357,000 | 3.5 |
| 500 | 16,100 | 6.0 | 8050 | 229,000 | 4.0 | 62000 | 108,000 | 9.1 |
| 125 | 3,570 | 8.0 | 2010 | 33,800 | 4.8 | 15500 | 26,000 | 4.9 |
| 31.3 | 937 | 6.4 | 503 | 5,860 | 5.6 | 3880 | 7,300 | 3.3 |
| 7.81 | 391 | 5.6 | 126 | 1,590 | 4.9 | 969 | 2,610 | 2.4 |
| 1.95 | 250 | 6.4 | 31.4 | 629 | 3.7 | 242 | 1,630 | 3.4 |
| 0.488 | 221 | 6.0 | 7.86 | 395 | 4.9 | 60.5 | 1,280 | 5.1 |
| 0.00 | 209 | 3.9 | 0.00 | 314 | 4.7 | 0.00 | 1,280 | 3.5 |

| KIM-1 - Spot 4 | | | Osteoactivin - Spot 5 | | | TFF3 - Spot 6 | | |
|----------------|------------|-----|-----------------------|------------|-----|---------------|------------|------|
| Conc. pg/mL | ECL Signal | %CV | Conc. pg/mL | ECL Signal | %CV | Conc. pg/mL | ECL Signal | %CV |
| 26500 | 478,000 | 2.2 | 47800 | 135,000 | 4.9 | 2400 | 154,000 | 6.3 |
| 6630 | 160,000 | 2.4 | 12000 | 43,200 | 5.7 | 600 | 33,600 | 4.2 |
| 1660 | 34,800 | 2.9 | 2990 | 11,800 | 5.8 | 150 | 7,390 | 5.4 |
| 414 | 7,420 | 3.7 | 747 | 3,360 | 6.1 | 37.5 | 1,820 | 4.8 |
| 104 | 1,820 | 3.2 | 187 | 1,360 | 4.3 | 9.38 | 679 | 7.8 |
| 25.9 | 533 | 3.2 | 46.7 | 900 | 9.6 | 2.34 | 350 | 10.0 |
| 6.47 | 220 | 5.0 | 11.7 | 746 | 4.5 | 0.586 | 266 | 13.0 |
| 0.00 | 117 | 7.3 | 0.00 | 687 | 4.0 | 0.00 | 248 | 19.0 |

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| VEGF - Spot 7 | | |
|---------------|------------|-----|
| Conc. pg/mL | ECL Signal | %CV |
| 2830 | 509,000 | 2.6 |
| 708 | 94,000 | 2.1 |
| 177 | 17,700 | 3.0 |
| 44.2 | 3,910 | 2.7 |
| 11.1 | 1,210 | 2.6 |
| 2.76 | 548 | 4.7 |
| 0.691 | 383 | 4.4 |
| 0.00 | 329 | 5.7 |

Components:


| Description | Lot Number | Storage Temperature | Expiration Date |
|--|------------------|---------------------|-----------------|
| Kidney Injury Panel 3 (human) Plate | Z0056458 | 2-8°C | 30 Jun 2021 |
| Anti-hu αGST Antibody | D0040822 | 2-8°C | 30 Jun 2022 |
| Anti-hu Calbindin Antibody | D0040823 | 2-8°C | 31 Aug 2022 |
| Anti-hu Clusterin Antibody | D0040824 | 2-8°C | 31 Aug 2022 |
| Anti-hu KIM-1 Antibody | D0040825 | 2-8°C | 30 Sep 2022 |
| Anti-hu Osteoactivin Antibody | D0040826 | 2-8°C | 30 Jun 2022 |
| Anti-hu TFF3 Antibody | D0040827 | 2-8°C | 30 Sep 2022 |
| Anti-hu VEGF Antibody | D0040828 | 2-8°C | 30 Jun 2022 |
| Kidney Injury Panel 3 (human) Calibrator Blend | A0040212 | ≤ -70°C | 31 Jan 2021 |
| Blocker A | Not Kit Specific | Not Kit Specific | N/A |
| Diluent 37 | M0370022 | ≤ -10°C | 31 Mar 2021 |
| MSD Read Buffer T | Not Kit Specific | Not Kit Specific | N/A |

Additional Comments:

| Assay | Spot | Specification | Comment |
|--------|------|---------------|--|
| 1 αGST | 1 | Control Conc. | Control-1 recovery 18.9% and control-2 recovery 7.3% |
| 2 αGST | 1 | Control CV | Interplate Control-2 CV 40.4% |

Statement:

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

| | Name | Function | Signature | Date |
|------------------------|--------------|----------|--|-------------|
| Review/Approval | Dawn Stollar | Quality |  | 01 MAY 2019 |