

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 1 (rat) Kit
Kit Catalog Numbers: K15162C-Series
Kit Lot Number: K0040453
Expiration Date: 31 Oct 2019

Acceptance Data/ Percent Recovery Specifications:

| Spot | Name | Calibrator | | Kidney Injury Panel 1 (rat) Control 1 | | Kidney Injury Panel 1 (rat) Control 2 | | Kidney Injury Panel 1 (rat) Control 3 | |
|------|-------------|------------|-------|---------------------------------------|-------|---------------------------------------|-------|---------------------------------------|-------|
| | | Recovery | CV | Recovery | CV | Recovery | CV | Recovery | CV |
| 1 | Lipocalin-2 | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 2 | Osteopontin | 80% - 120% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% | 75% - 125% | < 20% |
| 3 | Albumin | 80% - 120% | < 20% | 80% - 120% | < 20% | 80% - 120% | < 20% | 80% - 120% | < 20% |
| 4 | TIM-1 | 80% - 120% | < 20% | 80% - 120% | < 20% | 80% - 120% | < 20% | 80% - 120% | < 20% |

| Spot | Name | Value | LLOQ | | Value | ULOQ | |
|------|-------------|--------|------------|-------|-------|------------|-------|
| | | | Recovery | CV | | Recovery | CV |
| 1 | Lipocalin-2 | 1.56 | 70% - 130% | < 20% | 150 | 80% - 120% | < 20% |
| 2 | Osteopontin | 0.390 | 80% - 120% | < 20% | 37.5 | 80% - 120% | < 20% |
| 3 | Albumin | 781 | 80% - 120% | < 20% | 33200 | 80% - 120% | < 20% |
| 4 | TIM-1 | 0.0200 | 80% - 120% | < 20% | 1.88 | 80% - 120% | < 20% |

Acceptance Data/ Non Specific Binding Specifications:

| Spot | Name | Lipocalin-2 | Osteopontin | Albumin | TIM-1 |
|------|-------------|-------------|-------------|---------|--------|
| 1 | Lipocalin-2 | NA | < 1.0% | < 1.0% | < 1.0% |
| 2 | Osteopontin | < 5.0% | NA | < 1.0% | < 1.0% |
| 3 | Albumin | < 1.0% | < 1.0% | NA | < 1.0% |
| 4 | TIM-1 | < 1.0% | < 1.0% | < 1.0% | NA |

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Stock Concentration of Material Tested :

| Spot | Name | Item | Conc | Units |
|------|-------------|---------------------------------------|--------|-------|
| 1 | Lipocalin-2 | 20X Calibrator | 4600 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 1 | 1580 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 2 | 674 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 3 | 217 | ng/mL |
| 2 | Osteopontin | 20X Calibrator | 1036 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 1 | 442 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 2 | 86.6 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 3 | 16 | ng/mL |
| 3 | Albumin | 20X Calibrator | 980000 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 1 | 152300 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 2 | 77500 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 3 | 22500 | ng/mL |
| 4 | TIM-1 | 20X Calibrator | 197 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 1 | 19.9 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 2 | 3.3 | ng/mL |
| | | Kidney Injury Panel 1 (rat) Control 3 | 0.972 | ng/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:

| Lipocalin-2 - Spot 1 | | | Osteopontin - Spot 2 | | | Albumin - Spot 3 | | |
|----------------------|------------|-----|----------------------|------------|------|------------------|------------|-----|
| Conc. ng/mL | ECL Signal | %CV | Conc. ng/mL | ECL Signal | %CV | Conc. ng/mL | ECL Signal | %CV |
| 230 | 16,900 | 5.9 | 51.8 | 156,000 | 5.9 | 49000 | 425 | 5.2 |
| 76.7 | 8,990 | 3.1 | 17.3 | 47,700 | 2.9 | 16300 | 1,020 | 3.2 |
| 25.6 | 4,300 | 2.5 | 5.76 | 10,100 | 2.0 | 5440 | 2,510 | 3.5 |
| 8.52 | 2,250 | 2.1 | 1.92 | 2,380 | 2.1 | 1810 | 5,680 | 4.7 |
| 2.84 | 1,390 | 4.4 | 0.640 | 694 | 4.0 | 605 | 11,400 | 3.6 |
| 0.947 | 1,140 | 5.2 | 0.213 | 276 | 8.3 | 202 | 17,100 | 2.6 |
| 0.316 | 984 | 7.2 | 0.0711 | 151 | 7.3 | 67.2 | 21,600 | 2.2 |
| 0.00 | 959 | 4.2 | 0.00 | 80 | 14.0 | 0.00 | 24,300 | 3.7 |

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| TIM-1 - Spot 4 | | |
|----------------|------------|------|
| Conc. ng/mL | ECL Signal | %CV |
| 9.86 | 313,000 | 3.3 |
| 3.29 | 129,000 | 1.8 |
| 1.10 | 45,900 | 2.8 |
| 0.365 | 14,800 | 2.8 |
| 0.122 | 4,940 | 3.8 |
| 0.0406 | 1,710 | 5.7 |
| 0.0135 | 636 | 3.0 |
| 0.00 | 118 | 33.0 |

Components:

| Description | Lot Number | Storage Temperature | Expiration Date |
|--|------------------|---------------------|-----------------|
| Kidney Injury Panel 1 (rat) Plate | Z0055969 | 2-8°C | 30 Nov 2019 |
| Anti-rat Lipocalin-2 Antibody | D0040814 | 2-8°C | 31 Mar 2022 |
| Anti-rat Osteopontin Antibody | D0040815 | 2-8°C | 30 Jun 2022 |
| Albumin Tracer | D0040813 | 2-8°C | 31 Mar 2022 |
| Anti-rat TIM-1/KIM-1/HAVCR Antibody | D0040816 | 2-8°C | 31 Jul 2022 |
| Kidney Injury Panel 1 (rat) Calibrator Blend | A0040225 | ≤ -70°C | 30 Apr 2021 |
| Blocker A | Not Kit Specific | Not Kit Specific | N/A |
| Diluent 29 | M0290023 | ≤ -10°C | 31 Oct 2019 |
| MSD Read Buffer T | Not Kit Specific | Not Kit Specific | N/A |

Statement:

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

| | Name | Function | Signature | Date |
|------------------------|---------------|----------|--|-------------|
| Review/Approval | Karen Hamilla | Quality |  | 05 SEP 2019 |