Gentamicin (GEN) – Plasma, Serum
Beckman UniCel DxC Systems

Technical Procedure 3128

## Principle

### Intended Use

GEN reagent, when used in conjunction with UniCel® DxC 800 Systems and SYNCHRON® Systems Drug Calibrator 3 set, is intended for quantitative determination of gentamicin concentration in human serum or plasma.

### Clinical Significance

Gentamicin is an antibiotic used to treat serious gram-negative bacterial infections. Gentamicin therapy is monitored for effectiveness of the dose and possible nephrotoxicity.

### Methodology

GEN reagent is used to measure the gentamicin concentration by a particle enhanced turbidimetric inhibition immunoassay method.(1) Particle-bound drug (PBD) binds to gentamicin specific antibody (Ab) resulting in the formation of insoluble aggregates causing light scatter. Non-particle-bound gentamicin in the patient sample competes with the PBD for the antibody binding sites, inhibiting the formation of insoluble aggregates. The rate and amount of particle aggregation is inversely proportional upon the concentration of gentamicin in the sample.

The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 105 parts reagent. The system monitors aggregate formation by measuring the change in absorbance at 380 nanometers. This change in absorbance is inversely proportional to the concentration of gentamicin in the sample and is used by the System to calculate and express the gentamicin concentration based upon a multi-point calibration curve.

### Chemical Reaction Scheme


## Specimen

### Acceptable Sample Containers

13 x 75 Sodium Heparin BD tubes

Sodium Heparin microtainers

13 x 75 Red Top BD tubes

Red Top BD microtainers

### Unacceptable Sample Containers

Whole blood or urine and SST/PST samples

Serial samples should be collected using the same sample type (i.e., serum or plasma).

### Specimen Storage and Stability

Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.(3)

Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at 2°C to 8°C.

If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C.

**Frozen samples should be thawed only once**. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.(3)

### Sample Volume

The optimum volume, when using a 0.5 mL sample cup, is 0.3 mL of sample. For optimum primary sample tube volumes and minimum volumes, refer to the *Primary Tube Sample Template* for UniCel DxC Systems.

### Criteria for Unacceptable Specimens

Refer to the *Procedural Notes* section of this procedure for information on unacceptable specimens.

## Reagents

### Contents

Each kit contains the following items:

Two GEN Reagent Cartridges (2 x 100 tests) Kit Reorder 469137

#### Volumes per Test

| | |
|---|---|
| Sample Volume | 3 µL |
| Total Reagent Volume | 315 µL |

#### Cartridge Volumes

| | |
|---|---|
| A | 245 µL |
| B | 40 µL |
| C | 30 µL |

### Reactive Ingredients

Reagent Constituents

| | |
|---|---|
| Gentamicin Particle Reagent | 6.8 mL |
| Monoclonal anti-Gentamicin Antibody (mouse) | 4.7 mL |
| Gentamicin Reaction Buffer | 110.0 mL |

Also non-reactive chemicals necessary for optimal system performance

**CAUTION**

Sodium azide preservative may form explosive compounds in metal drain lines.
See NIOSH Bulletin: Explosive Azide Hazards (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

### Materials Needed but Not Supplied With Reagent Kit

SYNCHRON Systems Drug Calibrator 3 set

At least two levels of control material

Saline

### Reagent Preparation

No preparation is required. Do not mix.

Document lot number in reagent log; date and initial each cartridge before loading.

### Acceptable Reagent Performance

The acceptability of this reagent is determined by successful calibration and by ensuring that quality control results are within acceptance criteria, as defined in the Clinical Chemistry Quality Control Procedure #3000.T.

### Reagent Storage and Stability

GEN reagent when stored unopened at 2°C to 8°C, will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent is stable for 42 days at 2°C to 8°C unless the expiration date is exceeded. **DO NOT FREEZE.** Do not expose reagent to temperatures above 35°C or to direct sunlight.

## Equipment

This test is performed on the Beckman UniCel DxC 800 Systems; Beckman-Coulter, Brea, California. For technical assistance, call the Beckman-Coulter hotline: 1-800-854-3633.

Refer to the Beckman *UniCel DxC 800 systems Reference Manual* for detailed instructions.

## Calibration

### Calibrator Required

SYNCHRON® Systems Drug Calibrator 3 set (6 point calibration) Kit Reorder 471080

### Calibrator Preparation

No preparation is required. Mix contents with a gentle swirling motion and transfer the calibration solution into the sample cups. Recap calibrator bottles tightly and refrigerate when not in use. Do not mix caps among the various bottles in the calibrator set.

### Calibrator Storage and Stability

SYNCHRON® Systems Drug Calibrator 3 set is stable until the expiration date printed on the calibrator bottle if stored capped in the original container at 2°C to 8°C. Do not freeze.

**CAUTION**

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HbsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples to be handled as specified in Centers for Disease Control's Biosafety Level 2 guidelines.(4)

### Calibration Information

The system must have a valid calibration curve in memory before control or patient samples can be run.

Under typical operating conditions the GEN reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC800 System *Instructions For Use (IFU)* manual. This assay has within-lot calibration available. Refer to the UniCel DxC800 System *Instructions For Use* (IFU) manual for information on this feature.

For detailed calibration instructions, refer to the UniCel DxC800 System *Instructions For Use* (IFU) manual.

The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

**Traceability**

The measurand (GEN) in this calibrator is traceable to the Manufacturer's Working Calibrator. The Working Calibrator is prepared using processed human serum to which weighed-in quantities of gentamicin are added. The calibrator set is designed for generation of a six-point calibration curve which defines the analytical range for gentamicin. The traceability process is based on prEN ISO 17511.

The values were verified using representative samples from this lot of Calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

## Quality Control

A minimum of two levels of control material will be analyzed each day of patient testing.

In addition, controls should be run under the following circumstances:

Upon loading a new reagent cartridge.
Following each new calibration.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 System *Instructions For Use* manual.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

The following controls should be prepared and used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

| Control | Storage |
|---|---|
| MAS ChemTrak 1 | 2°C to 8°C |
| MAS ChemTrak 3 | 2°C to 8°C |

Controls are received frozen and stored at -10°C to -20°C.
Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days.

## Testing Procedure

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration may be required.
3. Program samples and controls for analysis.
4. After loading samples and controls onto the system, follow the protocols for system operation.

For detailed testing procedures, refer to the UniCel DxC800 System *Instructions For Use* (IFU) manual.

## Calculations

UniCel DxC Systems perform all calculations internally to produce the final reported result.

## Reporting Results

### Reference Intervals

Therapeutic GEN concentrations vary significantly, depending upon the individual. The lower limit for one patient may be ineffective in another, while the upper limit may prove toxic in a third. The physician should determine the appropriate reference interval for each patient. The reference intervals listed in the table below were taken from the literature. (5)

Reference Intervals

| Source | Sample Type | Drug Level | THERAPEUTIC INTERVAL Conventional Units | TOXIC INTERVAL Conventional Units |
|---|---|---|---|---|
| Literature | Serum/Plasma | **PEAK** | | >10 – 12 ug/mL |
| | | Less severe infection | 5 – 8 ug/mL | |
| | | Severe infection | 8 – 10 ug/mL | |
| | | **TROUGH** | | > 2-4 ug/mL |
| | | Less severe infection | < 1 ug/mL | |
| | | Moderate infection | < 2 ug/mL | |
| | | Severe infection | < 2-4 ug/mL | |

Refer to References (6,7,8) for guidelines on establishing laboratory-specific reference intervals.

The following comments will be automatically appended to GEN results by LIS:

**Gentamicin (Random)**, (canned text GENTTRAN2):

Random Gentamicin values can have a large range of values.
The Therapeutic Reference interval for PEAK values is 5.0 – 10.0 ug/mL and TROUGH values is <2.0 ug/mL.
Actual recommended therapeutic levels depend upon the treatment regimen for the patient.

**Gentamicin (Peak) and/or Gentamicin (Trough)**, (canned test GENTREAT)

Actual recommended therapeutic levels depend upon the treatment regimen for the patient.

## Procedural Notes

### Anticoagulant Test Results

The following anticoagulants were found by the manufacturer to be compatible with this method based on a study of 20 healthy volunteers. The data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

Acceptable Anticoagulants These samples types are for non-gel tubes only.

| Anticoagulant | Level Tested for In Vitro Interference | Average Plasma-Serum Bias (ug//mL) |
|---|---|---|
| Lithium Heparin | 14 Units/mL | NSI[a] |
| Sodium Heparin | 14 Units/mL | NSI |

[a]NSI = No Significant Interference (within ± 0.4 ug/mL or 10%) See Acceptable Sample Containers (page 1) for UCDH requirements.

**Interferences**

The following substances were tested by Beckman Coulter for interference with this methodology:

Interferences

| Substance | Source | Level | Observed Effect |
|---|---|---|---|
| Hemoglobin | RBC Hemolysate | 500 mg/dL | NSI[a] |
| Bilirubin | Porcine | 30 mg/dL | NSI |
| Rheumatoid Factor | Human | 300 IU/mL | NSI |
| Lipemia | Human | 4 + | NSI |
| Paraprotein (IgM) | Human | 500 mg/dL | NSI |

[a] NSI = No Significant Interference (within ± 2.6 µg/mL or 8%)

Refer to References (9,10,11) for other interferences caused by drugs, disease and preanalytical variables.

For assays employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the sample. Human anti-mouse antibodies may be present in samples from patients who have received immunotherapy or diagnostic procedures utilizing monoclonal antibodies or in individuals who have been regularly exposed to animals.(12,13) Additionally, other heterophile antibodies, such as human anti-goat antibodies may be present in patient samples. Interpretation of results should be done in the context of the overall clinical presentation of the patient, including symptoms, clinical history, data from additional tests and other appropriate information.

**Specificity**

The substances in the following table were added at the concentration listed to separate aliquots of a serum pool containing 6.4 µg/mL gentamicin. In most cases the value shown approximates maximum physiological concentrations. The recovered values were subtracted from the serum pool value. If the recovered results were within ± 2X of the within-run precision specifications there was no significant interference. If the recovered results were more than ± 2X of the within-run precision specifications the difference is listed under observed effect.

Specificity – Peak Gentamicin Level[a]

| Substance | Concentration (µg/mL) | Observed Recovery (mg/L) | Observed Effect (mg/L) |
|---|---|---|---|
| Amikacin | 70 | 6.5 | NSI[b] |
| Ampicillin | 100 | 6.3 | NSI |
| Carbenicillin | 250 | 7.1 | +11% |
| Cephalothin | 500 | 6.5 | NSI |
| Chloramphenicol | 50 | 6.6 | NSI |
| Clindamycin | 100 | 6.8 | NSI |
| Erythromycin | 40 | 6.5 | NSI |
| Kanamycin | 30 | 6.5 | NSI |
| Lincomycin | 100 | 6.4 | NSI |
| Neomycin | 60 | 6.3 | NSI |
| Netilmicin | 20 | 6.6 | NSI |
| Penicillin G | 50 | 6.5 | NSI |
| Sisomicin | 10 | 8.3 | +30% |
| Streptomycin | 60 | 6.3 | NSI |
| Sulfanilimide | 100 | 6.4 | NSI |
| Tetracycline | 500 | 6.5 | NSI |
| Tobramycin | 20 | 6.5 | NSI |
| Trimethoprim | 500 | 6.5 | NSI |
| Vancomycin | 100 | 6.4 | NSI |

[a] Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

[b] NSI = No Significant Interference (within ± 10%).

The substances in the following table were added at the concentration listed to separate aliquots of a serum pool containing 2.0 µg/mL gentamicin. In most cases the value shown approximates maximum physiological concentrations. The recovered values were subtracted from the serum pool value. If the recovered results were within ± 2X of the within-run precision specifications there was no significant interference. If the recovered results were more than ± 2X of the within-run precision specifications the difference is listed under observed effect.

Specificity – Trough Gentamicin Level[a]

| Substance | Concentration (µg/mL) | Observed Recovery (mg/L) | Observed Effect (mg/L) |
|---|---|---|---|
| Amikacin | 70 | 2.0 | NSI[b] |
| Ampicillin | 100 | 2.0 | NSI |
| Carbenicillin | 250 | 2.0 | NSI |
| Cephalothin | 500 | 2.0 | NSI |
| Chloramphenicol | 50 | 1.9 | NSI |
| Clindamycin | 100 | 2.0 | NSI |
| Erythromycin | 40 | 2.0 | NSI |
| Kanamycin | 30 | 2.2 | NSI |
| Lincomycin | 100 | 2.1 | NSI |
| Neomycin | 60 | 2.1 | NSI |
| Netilmicin | 10 | 2.1 | NSI |
| Netilmicin | 20 | 2.2 | NSI |
| Penicillin G | 50 | 2.1 | NSI |
| Sisomicin | 5 | 5.2 | +3.2% |
| Sisomicin | 10 | 7.9 | +5.9% |
| Streptomycin | 60 | 2.2 | NSI |
| Sulfanilimide | 100 | 2.1 | NSI |
| Tetracycline | 500 | 2.1 | NSI |
| Tobramycin | 20 | 2.1 | NSI |
| Trimethoprim | 500 | 2.1 | NSI |
| Vancomycin | 100 | 2.1 | NSI |

[a] Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

[b] NSI = No Significant Interference (within ± 0.4 ug/mL).

## Performance Characteristics

### Analytical Measurement Range

The UniCel DxC System(s) method for the determination of gentamicin provides the following analytical range.

Analytical Measurement Range (AMR)

| Sample Type | Range (µg/mL) |
|---|---|
| Serum or Plasma | 0.5 – 12.0 µg/mL |

### Clinical Reportable Range

Clinical Reportable Range (CRR) as determined at UCDHS

| Sample Type | Range (µg/mL) |
|---|---|
| Serum or Plasma | 0.5 – 50.0 µg/mL |

The analytical reportable range of this assay is 0.5 – 12.0 µg/mL.

Samples with concentrations greater than the AMR, > 12.0 ug/mL, will be diluted with saline and reanalyzed. Results are reported up to the Clinical Reportable Range (50.0 ug/mL).

Results from dilution exceeding the CRR are reported as **"> 50.0 ug/mL"**

Low GEN results from the instrument are set to "print" below the analytical limit down to the lowest reportable limit of 0.1 µg/mL. All samples with results **below 0.1 µg/mL ("less than" or "suppressed OIR low")** are to be confirmed by dilution. The messages window on the Remisol Data Manager screen will request that you make an offline dilution with ChemTrak1. Printed results between 0.1 µg/mL and 0.49 µg/mL do not need to be confirmed by dilution and are reported as "**< 0.5 µg/mL**".

**Dilution protocol:** Confirm a suspected low GEN sample result by adding one measured volume of test sample to an equal volume of a sample with known GEN concentration (MAS ChemTrak 1). The assayed GEN result multiplied by 2 of this diluted sample should be within ± 2SD of MAS ChemTrak 1 GEN mean. If the multiplied assayed result of the diluted sample is not within the acceptable control range, the GEN sample should be reported out as "***Unable to determine due to unknown interferences.***" (canned text **GINT**).
If the multiplied assayed result is within acceptable control range, manually enter the value 0.1 in Remisol as the GEN result. It will be reported as "**< 0.5 µg/mL**" in LIS.

Samples reported out as "SUPPRESSED" due to RXN ERROR should be reanalyzed.

### Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for GEN determination is 0.5 µg/mL.

### Equivalency

Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

As determined by Beckman

Serum or plasma (in the range of 0.5 to 7.9 µg/mL):

| | |
|---|---|
| Y (SYNCHRON LX Systems) | = 0.990X - 0.06 |
| N | = 75 |
| MEAN (SYNCHRON LX Systems) | = 2.81 |
| MEAN (SYNCHRON CX7 DELTA) | = 2.90 |
| CORRELATION COEFFICIENT (r) | = 0.990 |

As determined at UCDMC

Serum (in the range of 0.2 to 9.1 µg/mL):

| | |
|---|---|
| Y (DxC800-4449) | = 01.196X – 0.38 |
| N | = 54 |
| MEAN (DxC800-4449) | = 3.69 |
| MEAN (Abbott Architect) | = 3.41 |
| CORRELATION COEFFICIENT (r) | = 0.9762 |

Serum (in the range of 0.2 to 9.1 µg/mL):

| | |
|---|---|
| Y (UniCel DxC800-4427) | = 1.243X – 0.46 |
| N | = 54 |
| MEAN (UniCel DxC800-4427) | = 3.78 |
| MEAN (Abbott Architect) | = 3.41 |
| CORRELATION COEFFICIENT (r) | = 0.9764 |

Serum (in the range of 0.2 to 7.8 µg/mL):

| | |
|---|---|
| Y (UniCel DxC800-4118) | = 1.238X – 0.60 |
| N | = 49 |
| MEAN (UniCel DxC800-4118) | = 2.76 |
| MEAN (Abbott Architect) | = 2.71 |
| CORRELATION COEFFICIENT (r) | = 0.9756 |

Serum (in the range of 0.0 to 11.6 µg/mL):

| | |
|---|---|
| Y (UniCel DxC800-4449) | = 1.019X – 0.00 |
| N | = 60 |
| MEAN (UniCel DxC800-4449) | = 4.39 |
| MEAN (UniCel DxC800-4427) | = 4.47 |
| CORRELATION COEFFICIENT (r) | = 0.9930 |

Serum (in the range of 0.0 to 11.6 µg/mL):

| | |
|---|---|
| Y (UniCel DxC800-4427) | = 0.985X – 0.11 |
| N | = 45 |
| MEAN (UniCel DxC800-4427) | = 3.56 |
| MEAN (UniCel DxC800-4118) | = 3.39 |
| CORRELATION COEFFICIENT (r) | = 0.9953 |

Serum (in the range of 0.0 to 11.6 µg/mL):

| | |
|---|---|
| Y (UniCel DxC800-4449) | = 1.030X – 0.16 |
| N | = 45 |
| MEAN (UniCel DxC800-4449) | = 3.45 |
| MEAN (UniCel DxC800-4118) | = 3.39 |
| CORRELATION COEFFICIENT (r) | = 0.9954 |

Refer to References (14) for guidelines on performing equivalency testing.

**Precision**

A properly operating SYNCHRON® System(s) and UniCel DxC System(s) should exhibit imprecision values less than or equal to the following:

Precision Values as determined by Beckman

| Type of Precision | Sample Type | 1 SD | Changeover Value[a] | %CV |
|---|---|---|---|---|
| | | µg/mL | µg/mL | |
| Within-run | Serum/Plasma | 0.2 | 4.0 | 5.0 |
| Total | Serum/Plasma | 0.3 | 4.0 | 7.5 |

[a]When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

Precision established at UCDMC

| Type of Precision | Sample Type | n | Mean (µg/mL) | 1 SD | %CV |
|---|---|---|---|---|---|
| DxC800-4118 Within-run | MAS ChemTrak 1 | 20 | 8.21 | 0.16 | 1.9 |
| | MAS ChemTrak 3 | 20 | 1.60 | 0.08 | 4.7 |
| DxC800-4427 Within-run | MAS ChemTrak 1 | 20 | 8.57 | 0.11 | 1.3 |
| | MAS ChemTrak 3 | 20 | 1.63 | 0.06 | 3.9 |
| DxC800-4449 Within-run | MAS ChemTrak 1 | 20 | 8.73 | 0.11 | 1.2 |
| | MAS ChemTrak 3 | 20 | 1.68 | 0.07 | 4.0 |

| Type of Imprecision | Sample Type | n | Mean (µg/mL) | 1 SD | %CV |
|---|---|---|---|---|---|
| DxC800-4427 Day to Day | MAS ChemTrak 1 | 40 | 8.0 | 0.15 | 1.85 |
| | MAS ChemTrak 3 | 40 | 1.7 | 0.07 | 4.38 |
| DxC800-4449 Day to Day | MAS ChemTrak 1 | 40 | 8.4 | 0.14 | 1.71 |
| | MAS ChemTrak 3 | 40 | 1.7 | 0.09 | 5.46 |

Comparative performance data for a SYNCHRON LX® System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below. (15) Each laboratory should characterize their own instrument performance for comparison purposes.

Comparative performance as determined by Beckman

NCCLS EP5-T2 Precision Estimate Method

| Type of Imprecision | Sample Type | No. Systems | No. Data Points[a] | Test Mean Value µg/mL | EP5-T2 Calculated Point Estimates | |
|---|---|---|---|---|---|---|
| | | | | | SD | %CV |
| Within-run | Serum Control 1 | 1 | 80 | 2.2 | 0.1 | 5.3 |
| | Serum Control 2 | 1 | 80 | 6.1 | 0.1 | 1.8 |
| | Serum Control 3 | 1 | 80 | 9.7 | 0.2 | 2.0 |
| Total | Serum Control 1 | 1 | 80 | 2.2 | 0.2 | 7.1 |
| | Serum Control 2 | 1 | 80 | 6.1 | 0.2 | 2.5 |
| | Serum Control 3 | 1 | 80 | 9.7 | 0.2 | 2.1 |

[a]The point estimate is based on the pooled data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer's instructions.

**NOTICE**

These degrees of precision and equivalency were obtained in typical testing procedures on the SYNCHRON LX System and are not intended to represent the performance specifications for this reagent.

## Additional Information

For more detailed information on UniCel DxC Systems, refer to the UniCel DxC800 System *Instructions For Use* (IFU) manual.

## References

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| Prepared By | Date Adopted | Supersedes Procedure # |
|---|---|---|
| Kathy Dagang | | New<br>Test previously run at STC |

| Revision Date | Type of Revision | Revised by | Review/Annual Review Date | Reviewed By |
|---|---|---|---|---|
| | New | kdagang | | |
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