Procalcitonin (PCT) - Plasma
bioMérieux miniVIDAS® Immunoanalyzer

Technical Procedure 3280

Principle

Intended Use

VIDAS B·R·A·H·M·S PCT is an automated test for use on the bioMérieux miniVIDAS® Immunoanalyzer for the determination of human procalcitonin (PCT) in human plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. The VIDAS B•R•A•H•M•S PCT is intended for use in conjunction with other laboratory findings and clinical assessment, monitoring, and treatment of patients with severe sepsis and septic shock.

Summary and Explanation

Procalcitonin is the prohormone of calcitonin. Whereas calcitonin is only produced in the C cells of the thyroid gland as a result of hormonal stimulus, PCT is secreted by different types of cells from numerous organs in response to proinflammatory stimulation, particularly bacterial stimulation (1). Based on current literature, depending on the clinical background, a PCT concentration between 0.15 and 2.0 ng/mL does not necessarily exclude infection because localized infections may exhibit low levels (2-4). A PCT concentration > 2.0 ng/mL is suggestive of systemic bacterial infection, sepsis, or severe localized bacterial infection. These patients should be considered at risk of developing severe sepsis or septic shock (1-4).

Sepsis is an excessive reaction of the immune system and coagulation system to an infection (5). The diagnosis and monitoring of infected patients are major problems for physicians. It has been proven that PCT levels increase precipitously, specifically in patients with a bacterial infection. For laboratory diagnosis, PCT is an important marker enabling specific differentiation between a bacterial infection and other causes of inflammatory reactions (2). Moreover, the resorption of the septic infection is accompanied by a decrease in the PCT concentration, which returns to normal with a half-life of 24 to 35 hours (1,2,6,7).

In certain situations (e.g., newborns, polytrauma, burns, major surgery, prolonged or severe cardiogenic shock, etc.) PCT elevation may be independent of any infectious aggression. The return to normal values is usually rapid. Viral infections, allergies, autoimmune diseases and graft rejection do not lead to a significant increase in PCT (8).

However, a localized bacterial infection can lead to a moderate increase in PCT levels (2,9).

The evaluation of VIDAS B•R•A•H•M•S PCT assay results must always be performed taking into consideration the patient's clinical history and the results of any other tests performed.

If discrepancies are found between the laboratory findings and the clinical signs, additional tests should be performed.

Methodology

The assay principle combines a one-step immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips.

All of the assay steps are performed automatically by the instrument. The sample is transferred into the wells containing anti-PCT antibodies labeled with alkaline phosphatase (conjugate). The sample/conjugate mixture is cycled in and out of the SPR several times. This operation enables the antigen to bind with the immunoglobulins fixed to the interior wall of the SPR and the conjugate to form a sandwich. Unbound compounds are eliminated during washing steps.

Two detection steps are performed successively. During each step, the substrate (4-methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of antigen present in the sample.

At the end of the assay, results are automatically calculated by the instrument in relation to two calibration curves and corresponding to the two detection steps. A fluorescence threshold value determines the calibration curve to be used for each sample. The results are then printed out.

Acceptable Sample Containers

13 x 75 PST BD tubes
PST BD microtainers
Optimum volume: 0.5 mL, Minimum volume: 0.3 mL

Specimen Collection and Preparation

Type of Sample

Plasma (PST) is the required sample.

Other specimen types (serum) have not been evaluated and are currently unacceptable.

Observe the following recommendations for handling, processing, and storing blood samples(10):

1. Collect all blood samples observing routine precautions for venipuncture.
2. Mix the blood specimen by gently inverting the tube several times. **Clotted samples and under filled tubes are unacceptable. Sample tubes at least half full will be accepted**.
3. Keep tubes stoppered at all times.
4. Samples should be centrifuged and tested as soon as possible after collection.
5. Plasma samples (separated from the cells) may be stored for up to 48 hours refrigerated (2°C to 8°C) prior to testing.
6. For longer storage, separate and freeze plasma (cell free) at -20°C or colder in a non-defrosting freezer. Frozen samples are stable for up to 6 months. When thawing, allow samples to warm to room temperature for 30 minutes prior to testing. Mix plasma thoroughly and re-centrifuge if necessary.
7. Three freeze/thaw cycles have been validated.
8. Moderately-grossly hemolyzed samples are unacceptable for analysis. If a specimen appears to be more than slightly hemolyzed, the sample should be cancelled, and another specimen obtained and tested. Lipemia and icterus may also interfere with the assay. Append a specimen comment to the result.

Use the following guidelines when preparing specimens, unless instructed otherwise in the product insert:

- Ensure residual fibrin and cellular matter have been removed prior to analysis.
- Use laboratory posted settings for sample centrifugation of sample tubes.

Reagents

VIDAS B·R·A·H·M·S PCT Reagent Kit

Cat. No. 30 450-01: 60 determinations

- Provided ready to use.
- Store reagent kits at 2°C to 8°C.
- Stable until the expiration date stated on the label when stored at 2°-8°C.
- Store all unused reagents at 2-8°C. Carefully reseal the pouch after use with the desiccant inside to maintain stability of the SPRs, and return the complete kit to 2°-8°C.
- After opening the kit, check that the SPR pouch is correctly sealed and undamaged. If not, do not use the SPRs.
- Do not freeze reagents, with the exception of calibrators and controls after reconstitution.

The SPR®

The interior of the SPR® is coated during production with mouse monoclonal anti-procalcitonin immunoglobulins. Each SPR is identified by the "PCT" code. Only remove the required number of SPRs from the pouch and carefully reseal the pouch immediately.

The Reagent Strip

The strip consists of 10 wells covered with a labeled, foil seal. The label has a printed bar code which indicates the assay code, kit lot number and expiration date. The foil of the first well is perforated to facilitate the introduction of the sample. The wells in the center section of the strip contain the various reagents required for the assay. The last well of each strip is an optical cuvette in which the fluorometric reading is performed. Do not touch the last well of the strip.

Description of the PCT Strip

Wells	Reagents
1	Sample well
2 - 3 - 4	Empty wells
5	Conjugate: alkaline phosphatase-labeled mouse monoclonal anti-human procalcitonin immuno-globulins + preservative (400 µL)
6 - 7 - 8	TRIS NaCl Tween (pH 7.3) + preservative (600 µL)
9	Empty well
10	Reading cuvette with substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/L) + diethanolamine* (DEA*) (0.62 mol/L or 6.6%, pH 9.2) + 1g/L sodium azide (300 µL)

*** IRRITANT reagent:**
-R 36 : irritating to eyes.
-S 26 : in case of contact with eyes, rinse immediately with plenty of water and seek medical advice. For further information, refer to the Safety Data Sheet online.

Reagent Kit Composition

60 PCT strips	STR	Ready-to-use
60 PCT SPRs 2 X 30	SPR	Ready-to-use Interior of SPRs coated with mouse monoclonal anti-human procalcitonin immunoglobulins.
PCT controls C1 control 2 x 2 mL (lyophilized) C2 control 2 x 2 mL (lyophilized)	 C1 C2	Reconstitute with 2 ml distilled water. Let stand for 5-10 minutes then mix. Stable after reconstitution for 8 hours at 2°-8°C, or until the expiration date on the kit at - 25° ± 6°C. 5 freeze/thaw cycles are possible. TRIS NaCl buffer (pH 7.3) + recombinant human PCT + preservatives. The confidence interval in ng/mL is indicated on the MLE card after the following mention: Control C1 Dose Value Range" or "Control C2 Dose Value Range".
PCT calibrators S1 calibrator 2 x 2 mL (lyophilized) S2 calibrator 2 x 2 mL (lyophilized)	 S1 S2	Reconstitute with 2 ml distilled water. Let stand for 5-10 minutes then mix. Stable after reconstitution for 8 hours at 2°-8°C, or until the expiration date on the kit at - 25° ± 6°C. 5 freeze/thaw cycles are possible. TRIS NaCl buffer (pH 7.3) + recombinant human PCT + preservatives. The concentration in ng/mL is indicated on the MLE card after the following mention: "Calibrator (S1) Dose Value" or "Calibrator (S2) Dose Value", along with the confidence interval in "Relative Fluorescence Value" after the following mention: "Calibrator (S1) RFV Range" or "Calibrator (S2) RFV Range .
1 MLE card (Master Lot Entry)		Specifications for the factory master data required to calibrate the test: to read the MLE data, please refer to the *Operators Manual*.
1 Package insert		

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Materials Required But Not Provided

- Pipette with disposable tip to dispense 2 mL and 200 µL.
- Powderless, disposable gloves.
- For other specific materials, please refer to the Instrument Operator's Manual.
- bioMérieux miniVIDAS® Immunoanalyzer

Warnings and precautions

This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).

- Do not use the SPRs if the pouch is pierced. Carefully inspect the tip for a patent opening and do not use the SPR if the tip opening is plugged or obstructed.
- Do not use visibly deteriorated STRs (damaged foil or plastic).
- Do not use reagents after the expiration date indicated on the label.
- Do not mix reagents or disposables from different lots.
- Kit reagents contain 1 g/L sodium azide, which can react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- Use powderless gloves, as powder has been reported to cause false results for certain enzyme immunoassay tests.
- The substrate (well 10) contains an irritant agent (6.6% diethanolamine). Refer to the risk phrase "R" and the precautions "S" above.
- Spills should be wiped up thoroughly after treatment with liquid detergent and a solution of household bleach containing at least 0.5% sodium hypochlorite. Refer to the *VIDAS Operators Manual* for cleaning spills on or in the instrument. Do not place solutions containing bleach in the autoclave.
- The instrument should be routinely cleaned and decontaminated. Refer to the *VIDAS Operators Manual* for the appropriate procedures.

Equipment

This test is performed on the bioMérieux miniVIDAS® Immunoanalyzer; bioMérieux, Inc , Durham, NC. For technical assistance, call bioMérieux support: 1-800-682-2666.

Refer to the bioMérieux miniVIDAS® Immunoanalyzer *VIDAS Operators Manual* for detailed instructions.

Calibration

Calibration, using the two calibrators provided in the kit, must be performed each time a new lot of reagents is opened and with each new shipment of kits, after the master lot data (MLE) has been entered, and then every 28 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.
The calibrators, identified by S1 and S2, must be tested in duplicate (refer to the *VIDAS Operators Manual*) in the same run. The calibration values must be within the set RFV ("Relative Fluorescence Value"). If this is not the case, recalibrate using S1 and S2.

Quality Control

Two controls are included in each VIDAS B•R•A•H•M•S PCT kit. These controls must be analyzed immediately after opening a new kit to ensure that reagent performance has not been altered. Each calibration must also be checked using these controls. The instrument will only be able to check these control values if they are identified by C1 and C2.

Results cannot be validated if the control values deviate from the expected values. Samples tested in the same run must be re-assayed.

The following controls should be prepared and used in accordance with the package 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 the miniVIDAS Reagent Log sheets. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since obtaining the last acceptable quality control test point for this analyte.

Quality Control Material

Control	Storage
VIDAS PCT Control 1	Stable until the expiration date at -20°C or colder. Stable after reconstitution for 8 hours at +2°C to +8°C. Five (5) freeze-thaw cycles are acceptable.
VIDAS PCT Control 2	Stable until the expiration date at -20°C or colder. Stable after reconstitution for 8 hours at +2°C to +8°C. Five (5) freeze-thaw cycles are acceptable.

Freeze 1 mL aliquots of reconstituted controls at –20°C or colder.

In addition, for new shipments and reagent lot changes, patient comparisons should be run and evaluated for acceptability. Two patient samples that were run on the current lot should be retrieved with previous results of 0.15ng/mL and 2.0 ng/mL. After the new lot is calibrated and controls have been run, the patient samples should be run with the new lot. Results should agree within ±2 SD of a control range, or 20%, whichever is greater.

Instructions for Use

PCT Protocol data entry

When using the assay for the first time, and before reading the MLE data, scan the bar code(s) (at the end of the package insert) using the instrument bar code reader. This reading will allow VIDAS PTC protocol data to be transferred to the instrument software for its update. These data should only be read the first time the assay is used.

Master Lot data entry

Note: When using the assay for the first time, enter the VIDAS® PCT protocol (bar codes at the end of the package insert) before reading the MLE data. If the MLE data have been read before the VIDAS PCT protocol, read the MLE data again. Before each new lot of reagents is used, specifications (or factory master data) must be entered into the instrument using the master lot entry (MLE) data. If this operation is not performed before initiating the tests, the instrument will not be able to print results. The master lot data need only be entered once for each lot.

It is possible to enter MLE data manually or automatically depending on the instrument (refer to the *VIDAS Operators Manual*).

Assay Procedure

1. Remove the required reagents from the refrigerator. Use one "PCT" strip and one "PCT" SPR for each sample, control or calibrator to be tested. Be sure that the storage pouch has been carefully resealed after the required SPRs have been removed.
2. Insert one PCT SPR for each calibrator, control or patient sample to be run into the SPR block sleeves.
3. Label the strips with the control or sample ID.
4. Mix the calibrators and/or controls by inverting gently.
5. Pipette 200 µL calibrator, control, or sample into the first well of the PCT strip. Avoid forming bubbles in the well.
6. Gently insert the "PCT" SPRs and strips into the reagent strip tray on the instrument. Verify that the color labels with the assay code on the SPRs and the Reagent Strips match.
7. Push the SPR block closed.
8. Program the samples:
   a. Select [Status Screen].
   b. Select [Section A] or [Section B], depending on where the reagent strips and SPRs are loaded.
   c. Select the position for the test (numbered 1 through 6) using the numeric keypad.
   d. The calibrators must be identified by "S1" and by “S2”, and tested in duplicate. If the controls need to be tested, they should be identified by C1 and C2 and tested singly.
   e. Patient IDs may be entered by selecting [Sample ID], then using the barcode scanner, or they may be manually entered.
   f. For barcode numbers, use the appropriate keys on the keypad.
   g. For letters, use the arrow keys to move the box to the appropriate letter, and then press the round selection key next to the letter box to select the letter. Repeat until the Sample ID is complete.
   h. Press the enter key on the keypad (↵) to proceed to the next position.
   i. Repeat until all Sample IDs have been entered, or until you get to the last position (#6).
   j. After entering a sample ID in position #6, press the ENTER key twice (↵ ↵). If less than 6 samples are being tested, press the [Previous] key twice to return to the Load/Help screen.
9. Review the information on the screen for accuracy.
10. Press the [Start] selection button to begin the assay. The instrument will perform some preprocessing checks before initiating the run. The status light above the section (A or B) will turn solid green once the assay starts.
11. The assay will be completed within approximately 20 minutes. After the assay is completed, remove the SPRs and strips from the instrument. Dispose of the used SPRs and strips into an appropriate biohazard waste receptacle.

Results and Interpretation

Once the assay is completed, results are analyzed automatically by the computer using two calibration curves which are stored by the instrument; the concentrations are expressed in ng/mL.

As no international standard is available, VIDAS B•R•A•H•M•S PCT is calibrated against an internal panel of human sera with known procalcitonin concentrations. In case of patient follow-up, it is recommended to use the same PCT assay technique.

Limitations of the Method

Interference may be encountered with certain samples containing antibodies directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient's history and the results of any other tests performed.

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Range of Expected Values

Based on the literature (1-4), PCT levels between 0.15 and 2.0 ng/mL do not exclude an infection, because localized infections (without systemic signs) may be associated with such low levels. Levels >2.0 ng/mL are highly suggestive of systemic bacterial infection/sepsis or severe localized bacterial infection, such as severe pneumonia, meningitis, or peritonitis. With successful antibiotic therapy, PCT levels should fall with a half-life of 24 to 35 hours (1,2).

In cases of noninfectious elevations, PCT levels should begin to fall after 24 to 48 hours. Autoimmune diseases, chronic inflammatory processes, viral infections, and mild localized bacterial infections rarely lead to elevations of PCT of >0.5 ng/mL (8). Severe trauma, major burns, multi-organ failure, or major surgery can cause PCT elevations in the absence of sepsis.

Performance Characteristics

Analytical Measurement Range

The VIDAS B•R•A•H•M•S PCT measurement range is 0.05 to 200 ng/mL.

Detection Limits

The analytical detection limit, defined as the smallest concentration of procalcitonin which is significantly different from the zero concentration with a probability of 95%, is less than 0.05 ng/mL.

The PCT concentration measured with a 20% inter-lot (4 lots) coefficient of variation (functional detection limit) is 0.09 ng/mL.

Clinical Reportable Range

The VIDAS B•R•A•H•M•S PCT reportable range is **0.05-200 ng/mL**.

Samples with procalcitonin concentrations greater than 200 ng/mL shall be reported as "**> 200 ng/mL**".

Hook effect

No hook effect was found up to PCT concentrations of 2,600 ng/mL.

Reference Interval

< 0.15 ng/mL

NOTE: Procalcitonin levels should be used along with other clinical information for sepsis and antimicrobial stewardship. The reference intervals are not validated for neonates and patients with burn injury.

Studies evaluating various populations (e.g., emergency, surgery, community acquired pneumonia, intensive care unit, endotoxin challenged) without sepsis corresponded with reference interval of < 0.15 ng/mL. All studies were performed with the B•R•A•H•M•S PCT test on serum. The reference range does not apply to neonates or patients with burn injury.

Methods Comparison

Concordance with the B·R·A·H·M·S PCT LIA method

A concordance study between VIDAS B·R·A·H·M·S PCT and B·R·A·H·M·S PCT LIA was performed using 204 samples with cut-off values at 0.5 ng/mL and 2 ng/mL.:

VIDAS B·R·A·H·M·S PCT (PCT)	B·R·A·H·M·S PCT LIA		
	≤ 0.05 ng/mL	> 0.05 ng/mL	Total
≤ 0.05 ng/mL	74	1	75
> 0.05 ng/mL	5	124	129
Total	79	125	204

VIDAS B·R·A·H·M·S PCT (PCT)	B·R·A·H·M·S PCT LIA		
	≤ 2 ng/mL	> 2 ng/mL	Total
≤ 2 ng/mL	109		
> 2 ng/mL	8		
Total			

The percentages of concordance between the 2 techniques for the cut-offs at 0.5 and 2 ng/mL are respectively 97.1% and 94.1%.

As determined by UCDMC:

A study was performed at UCDMC comparing 40 patients with suspected sepsis. Patients were derived from the emergency department and intensive care units. Clinical conditions included respiratory tract, bloodstream, urinary tract, and wound infections. Procalcitonin was measured on the MiniVidas at UCDMC and compared to the B·R·A·H·M·S PCT LIA at ARUP.

Plasma (in the range of 0.08 to 6.64 ng/mL)

Y (MiniVIDAS)	= 1.22 (ARUP) – 0.07
Correlation Coefficient (R)	= 0.97
Mean (SD) Bias	= 0.13 (0.42) ng/mL
Sample Size (n)	= 40

Clinical Performance

A study performed on four (4) sites (2 in France and 2 in the USA) determined the clinical performance of the VIDAS B·R·A·H·M·S PCT This study included 232 patients (143 males and 89 females), who were consecutively admitted to the medical intensive care unit (MICU) on their first day of admission. The data represents first day admission testing. Patients admitted for trauma, surgery, burns, or prolonged or severe cardiogenic shock were excluded from the study.

Based on criteria from the consensus conference of the American College of Chest Physicians/Society of Critical Care Medicine (5), patients were classified into 5 categories: no infection, SIRS (Systemic Inflammatory Response Syndrome), sepsis, severe sepsis and septic shock.

The number, range and mean age in each category were as follows:

- no infection: 35 patients aged between 22 and 92 years (mean 62.5 years)
- SIRS: 69 patients aged between 18 and 92 years (mean 58.7 years)
- sepsis: 24 patients aged between 21 and 86 years (mean 59.7 years)
- severe sepsis: 49 patients aged between 33 and 89 years (mean 69.1 years)
- septic shock: 55 patients aged between 33 and 88 years (mean 68.3 years)

PCT values for the groups of patients with no infection or SIRS or sepsis versus severe sepsis or septic shock with cut-offs at 0.5 ng/mL and 2.0 ng/mL are shown in the tables below:

Results obtained with a cut-off at 0.5 ng/mL:

	No infection / SIRS / sepsis	Severe sepsis / septic shock	Total
PCT ≤ 0.5 ng/mL	74	18	92
PCT > 0.5 ng/mL	54	86	140
Total	128	104	232

Results obtained with a cut-off at 2.0 ng/mL:

	No infection / SIRS / sepsis	Severe sepsis / septic shock	Total
PCT ≤ 2 ng/mL	98	37	135
PCT > 2 ng/mL	30	67	97
Total	128	104	232

Precision

Six serum samples were tested in duplicate in 20 different runs (2 runs per day) with 2 reagent lots using the same instrument at three sites (N=240).

The repeatability (intra-run precision), inter-run reproducibility (inter-run precision), inter-site reproducibility (inter-site precision) and inter-lot reproducibility (total precision = intra-run, inter-run, inter-day, inter-site, inter-lot) were calculated using this protocol, based on the recommendations of CLSI EP5-A2 document:

Sample	Mean Concentration (ng/mL)	Standard Deviation	CV (%)	Standard Deviation	CV (%)	Standard Deviation	CV (%)	Standard Deviation	CV (%)
Sample 1	0.22	0.01	4.61	0.02	7.04	0.02	11.40	0.02	11.40
Sample 2	0.46	0.02	3.27	0.02	5.29	0.04	7.86	0.04	7.86
Sample 3	1.91	0.04	2.08	0.07	3.63	0.11	5.86	0.12	6.17
Sample 4	24.35	0.47	1.93	0.87	3.57	1.03	4.21	1.50	6.18
Sample 5	56.69	1.77	3.13	2.35	4.15	2.96	5.22	3.95	6.96
Sample 5	154.73	6.98	4.51	10.32	6.67	15.17	9.81	23.69	15.31

Precision established at UCDMC

Specificity

The following compounds, tested at the concentrations indicated in the table, do not affect the VIDAS B·R·A·H·M·S PCT test.

Tested Compound	Tested Concentration
Protein (albumin)	4 g/dL
Human Calcitonin	60 ng/mL
Human Katacalcin	10 ng/mL
Human a-CGRP*	10 ng/mL
Human a-CGRP*	10 ng/mL

**Calcitonin Gene Related Peptide*

Drug interference

The following drugs, at the concentrations indicated in the table, do not affect the VIDAS B•R•A•H•M•S PCT test:

Tested Drug	Tested Concentration
Imipenem	0.5 mg/mL
Cefotaxime	180 mg/dL
Vancomycin	3 mg/mL
Dopamine	26 mg/dL
Noradrenalin	4 µg/mL
Dobutamine	22.4 µg/mL
Heparin	16,000 U/L
Furosemide	4 mg/dL

Accuracy

The test linearity was studied according to a procedure taken from the CLSI EP6-A guideline. The test is linear over the complete measurement range.

Three samples were diluted in a PCT-negative serum pool and tested in triplicate. The ratio of the mean concentration measured over the expected mean concentration is expressed as a mean recovery percentage.

Samples	Dilution Factor	Mean Expected Concentration (ng/mL)	Mean Measured Concentration (ng/mL)	Mean Recovery Percentage (%)
1	1/1	137.07	137.07	100.0
	1/2	68.54	71.54	104.4
	1/3	45.69	49.56	108.5
	1/4	34.27	37.26	108.7
	1/8	17.13	19.50	113.8
	1/16	8.57	8.75	102.2
	1/20	6.85	7.73	112.8
2	1/1	38.67	38.67	100.0
	1/2	19.34	19.75	102.1
	1/3	12.89	13.90	107.8
	1/4	9.67	9.79	101.3
	1/8	4.83	4.96	102.5
	1/16	2.42	2.26	93.3
	1/20	1.93	1.85	95.7
3	1/1	7.58	7.58	100.0
	1/2	3.79	4.17	110.1
	1/3	2.53	2.70	107.0
	1/4	1.90	1.98	104.7
	1/8	0.95	0.94	99.2
	1/16	0.47	0.51	108.4
	1/20	0.38	0.37	98.5

Waste Disposal

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.

It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

References

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10. Package Insert US- 13975 - A - en - 30450-01-imp

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Prepared By	Date Adopted	Supersedes Procedure #
kdagang	12/18/2014	New

Revision Date	Type of Revision	Revised by	Review/Annual Review Date	Reviewed By
12/18/2014	New Procedure	kdagang	12/18/2014	L. Howell
03/20/2015	specimen dilution clarification	kdagang	04/15/2015	J. Gregg