Manual Dilution Policy

Purpose

This policy covers performance of any assay when the result is greater than the analytical measurement range (AMR) or greater than the instrument on-board dilution, e.g., ORDAC, as applicable, and the sample is manually diluted before repeating the assay to obtain a numeric value.

Scope

This policy includes any assay for which the measured value may exceed the established analytical measurement range (AMR) or the instrument on-board dilution, as applicable, and requires manual dilution of the patient sample to report a clinically useful result.

Definition

Analytical Measurement Range (AMR): the range of analyte values that a method can directly measure on the specimen without any dilution or concentration.

Over Range Detection and Correction (ORDAC): the instrument on board dilution established for an assay when initial testing measurement is greater than the AMR. ORDAC is primarily defined for Beckman instruments.

Background

A measured value that is outside the AMR or the instrument on-board dilution may be unreliable and should not be reported in routine practice. Dilution or concentration of a sample may be required to achieve a measured analyte activity or concentration that falls within the AMR.

Policy

The laboratory director is responsible for establishing the maximum result based on established dilution protocol for clinical use.

For analytes with laboratory results outside the limits of the AMR or on-board dilution's high range, the SCPMG Laboratory Systems has specified a 10 (ten) fold dilution as the maximum dilution for the assays listed (see List of Tests), except as noted.

Occasionally, upon the request of a provider or on a case by case basis and with the approval of the laboratory director, the laboratory may manually dilute patient samples greater than x10 dilution or any test not included in the list below.

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Manual Dilution Policy, Continued

Policy, continued

If a manual dilution is required, dilute the specimen as specified in the assay procedure, up to the maximum dilution allowed. The diluted or concentrated result must be within the AMR before it is mathematically corrected by the dilution factor to obtain a reportable numeric result.

- When the diluted result is within the AMR, multiply by the dilution factor and report the result.
- If the result obtained using the maximum dilution allowed is greater than the AMR:
  - Report the result as greater than (>) the highest reportable value of the AMR, i.e., >120
  - Enter a Result Comment to report the result multiplied by the dilution factor, and add text: Verified by dilution, i.e., 1400 mg/dL Verified by dilution

Selection of the diluent is important because the matrix of the specimen should be maintained. The laboratory must follow the manufacturer's recommendation of which diluent to use with out-of-range specimens.

For general chemistry tests mentioned in this policy, *deionized water* or *isotonic saline* is an acceptable diluent.

Allowable dilutions and concentrations are established when a method is first placed into service, as applicable; or when requested by a clinician or medical group based on clinical necessity after the SCPMG Laboratory Systems have evaluated clinical appropriateness.

Established allowable dilution protocol is reviewed biennially thereafter.

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Manual Dilution Policy, Continued

List of Tests

The tables which follow list the tests that are included in this policy.

Test/Assay Name

• Glucose on the Beckman instrument
• Lipase on the Vitros instrument
• LDH, Lactate, and Urine Total Protein on all platforms
• ALT on all platforms
• Magnesium on all platforms
• CK on all platforms [may be diluted greater than x10 on a case by case basis or upon the request of a clinician]
• HCG (quantitative) on all platforms
• TDMs performed at the Medical Centers:
  • Acetaminophen
  • Salicylate
  • Phenobarbital
  • Tegretol (Carbamazepine)

Test/Assay Name

• TDMs performed at the Medical Centers, continued:
  • Valproic Acid (Depakene)
  • Dilantin (Phenytoin)
  • Theophylline
  • Vancomycin
  • Gentamycin
  • Digoxin
  • Tobramycin
• CBC Platforms (HGB, WBC, Platelet)
  • LH750 (up to 1:5)
  • XE2100 (up to 1:5)
  • HMX (up to 1:10)
  • XT1800i (up to 1:5)
  • AcT5 (up to 1:10)
 	
Note: Body Fluids will not be diluted.

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Manual Dilution Policy, Continued

List of Tests, continued

Test/Assay Name
Tests performed at the RRL: • Alcohol, Ethyl • Amikacin • Amitriptyline • Benzodiazepine • Carbamazepine (Tegretol) • Chlordiazpoxide (Librium) • Clorazepate (Tranxene) • Cyclosporine • Desipramine • Diazepam (Valium) • Digoxin • Doxepin • Ethosuximide (Zarontin) • Imipramine • Lidocaine • Lithium • Methotrexate • MicroAlbumin • Nortriptyline • Phenobarbital (Luminal) • Phenytoin (Dilantin) • Phenytoin, Free (Dilantin, Free) • Primidone (Mysoline) • Sirolimus • Tacrolimus • Thiocyanate • Tobramycin • Total T3 • TSH • Tranxene • Trazodone • Tricyclic Confirmation • Triglycerides • Valproic Acid • Vancomycin • Volatiles

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Manual Dilution Policy, Continued

Non-Controlled Documents

The following non-controlled documents support this policy.

- CAP Laboratory Accreditation Standards Checklist
- CMS CLIA Regulations and Interpretive Guidelines for Laboratories

Controlled Documents

The following controlled document supports this policy.

Policy	
Document Number	**Document Name**
QM 5.5.2.100	Method Validation Policy

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HISTORY PAGE

Type of Change: New Major, Minor	Description of Change(s)	Quality Systems Leader/Date	Operations Director, Area Laboratory Review/Date	Laboratory Director Review/Date	Date Change Implemented
Version 03	• Added language for results greater than AMR using maximum dilution allowed and how to report results • Formatting changes		5.8.15	5/11/15	

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Reviewed and approved by (for Medical Center Area Approval Only):

SIGNATURE	DATE
Name: _____ **Operations Director, Area Laboratory**	5.8.15
Name: _____ **CLIA Laboratory Director**	5-11-'15

Signature Manifest

Document Number: SCPMG QMS - 0024 **Revision:** 3
Title: Manual Dilution Policy

All dates and times are in Pacific Standard Time.

Manual Dilution Policy

Initial Approval

Name/Signature	Title	Date	Meaning/Reason
Fred Ung (K057175) Maureen Ahler (K083442)	Quality Systems Leader	14 Mar 2014, 10:26:44 AM	Approved

Final Approval

Name/Signature	Title	Date	Meaning/Reason
Gary Gochman (P091953) Darryl Palmer-Toy (T188420)	RRL MEDICAL DIRECTOR	20 Mar 2014, 04:51:42 AM	Approved

Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Maureen Ahler (K083442)	Quality Systems Leader	20 Mar 2014, 07:42:19 AM	Approved