

I. REPORTABLE RANGES.

The Laboratory must verify and confirm the reportable range of each quantitative test before the assay is reported as a patient result. It must establish the lowest reportable concentration and the highest reportable concentration without diluting a patient's sample. The lowest reportable range is not necessarily the lowest calibration concentration.

- ☆ The reportable range includes all results that may be reliably reported. This includes **Analytical Measurement Range**, which is the range of analyte values that a method can directly measure with accuracy and without dilution of patient sample. It also includes the **Clinically Reportable Range**, is the range that is clinically acceptable and that might require a dilution.
- ☆ The ANALYTICAL MEASUREMENT RANGE (AMR) is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process
- ★ The **Analytical Measurement Range** is determined by calibration and calibration verification. It is the value at which the test could be reported with accuracy, or might be considered the "linearity or accuracy of the instrument for that analyte". We use this quantity in our lab to determine at what point a dilution of a specimen must be performed in order for the patient result to be reported. * (See chart at end of procedure)
- ☆ The CLINICALLY REPORTABLE RANGE (CRR) is the range of analyte values that a method can measure, allowing for specimen dilution, concentration, or other pretreatment used to extend the direct analytical measurement range
- ★ The **Clinically Reportable Range** is determined by clinical relevance. This value cannot be outside of the accuracy determined for that test, without a dilution. When a dilution is performed, it is reported with a comment added to the result stating that a specimen dilution was performed. * (See chart at end of procedure)
- ☆ The limits of the measurement range are determined by meeting accuracy and precision on results for the analytes, when applicable. The reportable range must be verified using at least a minimal value, a midpoint value and a maximum value.
- ☆ The reportable range is sometimes determined by clinically relevant limits, though these might be narrower than the potential analytical range. This is true especially in lower limits. With some analytes, dilutions allow the reportable range to be higher than the analytical range
- ☆ All Reportable ranges are reviewed with the Medical Director periodically, in order to determine meaningful clinical values.
- ☆ IF a test result from an instrument is less than or greater than the reportable range, it is reported as less than or greater than with the number of the low an high reportable range. For example if the reportable range on a test is 10-400. Any result less than 10 would be reported as such, and any result greater than 400 would be reported as >400.
- ☆ Any test reported after a dilution has been made is reported that the result is from a diluted specimen. Once the diluted test result reaches the clinically reportable higher limit, the analyte will be reported out as "greater than" and the reportable value.
- ☆ The analytical measurement range and the reportable range must be established before implementing a new assay, when applicable.

II. REFERENCE RANGES (NORMAL VALUES).

Reference ranges allow the clinician to compare patient results to a specific population or normal reference. These must be either established, or established and verified for each reported analyte and any time a new methodology is used. Criteria for evaluation of reference ranges include all of the following.

- ☆ Beginning the testing of a new analyte.
- ☆ Change of methodology in an analyte already being reported.
- ☆ Change in instrumentation that an analyte is being performed.
- ☆ Change in patient population.
- ☆ For some analytes, a new reagent lot number prompts verification of and sometimes a change in established reference ranges (such as change in coagulation reagent lot numbers.)

- ☆ For some analytes, especially therapeutic drugs and certain tests that are performed very rarely, manufacturer's information is used to establish reference ranges.
- ☆ For most Pediatric reference ranges, these are used from published literature.
- ☆ For whole blood glucose the published ranges are used for adults, and Pediatricians were consulted for the Newborn ranges.
- ☆ Periodically reference ranges are re-evaluated in order to verify that they are still appropriate. This is especially true with coagulation testing. However, anytime we see shifts in values from our patient population, we re-evaluate the ranges. The reference ranges are revised when needed and physicians are notified of the change. Coagulation reference ranges are reviewed and revised if needed at least annually when new reagent lot numbers are correlated.
- ☆ Reference ranges are included as a part of the patient report for each applicable analyte. In different clinical areas, the basis for determining the Reference Ranges documented in population studies. Every other year, in chemistry the Reference Range Service is purchase through CAP proficiency testing in order to compare reference ranges of most chemistry testing.
- ☆ The Medical Director of the Laboratory is consulted about reference ranges and approves reference ranges by reviewing correlations with new instruments, population studies, technical procedures including the reference ranges, and the Reference Range CAP proficiency testing.

The Medical Director of the Laboratory Services at Brownwood Regional Medical Center has approved the following Clinical Reportable Ranges. Any addition of an applicable analyte will be approved before the test is used to report patient results.

ANALYTICAL MEASUREMENT RANGE (LINEARITY) AND
CLINICAL REPORTABLE RANGE FOR ALL APPLICABLE CHEMISTRY ANALYTES

TEST	ANALYTICAL MEASUREMENT RANGE	AUTO DILUTION	UPPER LIMIT W/ AUTO DILUTION	MANUAL DILUTION USED	CLINICALLY REPORTABLE RANGE
ACETAMINOPHEN	2.0-300	None	NA	6	2.0-1800
ALBUMIN, PLASMA OR SERUM	0.6-8.0	None	NA	None	0.6-6.0
ALCOHOL	10-300	1.5	450	None	10-450
ALKALINE PHOSPHATASE	11-1000	2.3	2300	20	11-20000
ALT	0-1000	2	2000	20	14-20000
AMMONIA	0-1000	None	NA	None	0-1000
AMYLASE	0-650	2	1300	30	2-195000
AST	0-1000	2	2000	20	6-20000
BNP	5-5000	None	NA	None	15-5000
BUN	0-150	1.5	225	None	0-225
CALCIUM	5.0-15.0	1.7	25.5	None	5.0-25.5
CARBAMAZEPINE	0.5-20	1.5	30.0	None	0.5-30
CEA	0.15-550	5	2750	None	0.15-2750
CHLORIDE	50-200	None	NA	None	75-200
CHOLESTEROL	50-600	1.5	900	3	50-1800
	7-1000	2	2000	40	7-40000

TEST	ANALYTICAL MEASUREMENT RANGE	AUTO DILUTION	UPPER LIMIT W/ AUTO DILUTION	MANUAL DILUTION USED	CLINICALLY REPORTABLE RANGE
CK					
CO ₂	5-45	None	NA	None	5-45
CORTISOL	1.0-50	5	250	None	1.0-250
CREATININE	0-20	2	40	None	0-40
DIRECT BILIRUBIN	0-12.0	2	24.0	None	0.05-24.0
DIGOXIN	0.06-5.0	None	NA	None	0.06-5.0
ESTRADIOL	20-2000	3	6000	None	20-6000
FERRITIN	0-1100	20	22,000	100	1-110000
FOLATE	1.0-24	None	NA	None	1.0-24
FSH	0.1-170	None	NA	None	0.1-170
GENTAMYCIN	0-12	None	NA	2	0.2-24
GGT	0-800	1.5	1200	20	7-16,000
GLUCOSE	0-500	1.5	750	3	20-1500
HCG	0.4-5000	40	200,000	200	0.4-1000000
HDL	3-150	None	NA	None	3-150
HEMOGLOBIN A ₁ C	Assay range*	None	NA	3.6*	>15*
IRON	5-1000	None	NA	2	5-2000
IRON BINDING	0-1000	None	NA	2	6-2000
LACTIC ACID	0.3-15	2	30	None	0.3-30
LDH	6-1000	2	2000	10	1-10000
LH	0.05-200	None	NA	None	0.05-200
LIPASE	10-1500	2	3000	30	50-45000
LITHIUM	0.2-5.0	None	NA	2	0.2-10.0
MAGNESIUM	0-20	None	NA	None	0-20
MMB	0.5-300	2	600	None	0.5-600

TEST	ANALYTICAL MEASUREMENT RANGE	AUTO DILUTION	UPPER LIMIT W/ AUTO DILUTION	MANUAL DILUTION USED	CLINICALLY REPORTABLE RANGE
OSMO SERUM	100-2000	None	NA	None	100-1600
OSMO URINE	100-2000	None	NA	None	100-1600
PHENOBARBITOL	1.0-80	2	160	4	1.0-320
PHENYTOIN	2.5-40	None	NA	4	2.5-160
PHOSPHORUS	0-9.0	1.5	13.5	2	0.2-18.0
POTASSIUM	1.0-10.0	None	NA	None	1.0-9.0
PSA	0.085-150	5 10 (MUST PROGRAM THIS DILUTION)	750/1500	None	0.085-1500
RUBELLA	5.0-400	None	NA	3	5.0-1200
SALICYLATE	2-100	3	300	None	2-300
SODIUM	50-200	None	NA	None	100-200
T3 UPTAKE	15-68	None	NA	None	15-68
T4	0.5-24	None	NA	None	0.5-24
T4 FREE	0.18-6.0	None	NA	None	0.18-6.0
TESTOSTERONE	20-1600	3	4800	None	20-4800
THEOPHYLLINE	2.0-40.0	None	NA	None	2.0-40.0
TOTAL BILIRUBIN	0-25	2	50	None	0.04-50
TOTAL PROTEIN (SERUM/PLASMA)	2.0-12.0	None	12.0	None	2.0-12.0
TOTAL PROTEIN (BODY FLUID)	2.0-12.0	None	12.0	2	2.0-24.0
TRIGLYCERIDE	15-1000	2	2000	None	15-2000
TROPONIN I	0.04-40.0	None	NA	None	0.04-40.0
TSH	0.01-50.00	2	100	None	0.01-100.00
URIC ACID	0-20	3.4	68	None	0.1-68
URINE AMYLASE (instrument Auto dilutes the specimen X 10 when run on urine mode)	0-200	None	NA	10	2000
URINE/CSF PROTEIN	6-250	2	500	6	6-1500
URINE CHLORIDE	10-330	None	NA	2	10-660

TEST	ANALYTICAL MEASUREMENT RANGE	AUTO DILUTION	UPPER LIMIT W/ AUTO DILUTION	MANUAL DILUTION USED	CLINICALLY REPORTABLE RANGE
URINE CREATININE (instrument Auto dilutes the specimen X 10 to run on urine mode)	0-650	None	NA	2	0-1300
URINE POTASSIUM	1-300	None	NA	2	1-400**
URINE SODIUM	5-300	None	NA	2	5-600
VALPROIC ACID	3-150	1.5	225	None	3-225
VANCOMYCIN	0.8-50	None	NA	2	0.8-100
VITAMIN B12	150-1000	5	5000	None	150-5000

* Hemoglobin A_{1c} is not reported in g/dl, it is reported in percentage of hemoglobin A_{1c} to hemoglobin A. The analytical range cannot specifically be defined. However, if you get an assay range flag when performing the test, the test will be diluted only 1:1 with saline and rerun. Because of the calculation of the test, it is not necessary to multiply by the dilution factor. This is a part of the ratio. Do not report out any result greater than 15 or less than 3.6. Remove the result, use the comment > than the reportable range, and report > 15, or less than 3.6 if applicable.

** Have only verified urine Potassium up to 200.

**ANALYTICAL MEASUREMENT RANGE (LINEARITY) AND CLINICAL REPORTABLE RANGE FOR ALL APPLICABLE HEMATOLOGY ANALYTES
(Body Fluid Cell counts are performed only on the Sysmex 5000)**

ANALYTE	ANALYTICAL MEASUREMENT RANGE (LINEARITY)	CLINICAL REPORTABLE RANGE
WBC	0-440.0 K/ μ L	0.5-200 K/ μ L
RBC	0-8 M/ μ L	0.5-8 M/ μ L
HEMOGLOBIN	0-25 g/dL	2.5-25 g/dL
HEMATOCRIT	0-75.0%	6-75%
PLATELET COUNT	0-5000 K/ μ L	5-5000 K/ μ L
NRBC	0-464/100 WBC	0-464/100 WBC
RETIC	0-23.0%	0.2-23.0%
SED RATE	0-120 mm/hr	0-120 mm/hr
WBC-BODY FLUID	0.10.0 K/ μ L	0.001-10 K/ μ L
RBC-BODY FLUID	0-5.00 M/ μ L	0.003-5.00 M/ μ L

ANALYTICAL MEASUREMENT RANGE (LINEARITY) AND CLINICAL REPORTABLE RANGE FOR ALL APPLICABLE COAGULATION ANALYTES

MANUFACTURER DETECTION TIME (LINEARITY) FOR CA 1500	LABORATORY APPROVED CLINICAL REPORTABLE RANGE FOR CA 1500.
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LABORATORY STANDARD OPERATING PROCEDURES MANUAL	LABORATORY REPORTING RANGES AND REFERENCE RANGES
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PT – 7.0-300.0 SECONDS	PT'S GREATER THAN 100.0 SECONDS ARE REPORTED AS >100.0 SECONDS. (INR IS REPORTED AS >11.0) PT'S LESS THAN 7.5 SECONDS ARE REPORTED AS <7.5 SECONDS.
PTT – 17.3-600.0 SECONDS	PTT'S GREATER THAN 150 SECONDS ARE REPORTED AS >150 SECONDS. PTT'S 17.3 SECONDS OR LESS ARE NOT REPORTABLE. (PERFORM ON BACKUP ANALYZER OR SEND TO REFERENCE LAB.)
FIBRINOGEN. Calibration is performed at least every 6 months. The linearity is based on the Fibrinogen curve. It will be approximately, 62 mg/dl-500 mg/dl, For results 450mg/dl and higher ,analyzer auto redilutes (1.20 dilution) ; for 50mg/dl & below, performs auto redilution (1.5 dilution)	FIBRINOGEN.65 mg/dl to 1000 mg/dl. (AMR) If less than 65, report as <65 mg/dl If greater than 1000 mg/dl, perform on ACL 3000 for a result up to 1,600 mg/dl (when diluting 1.1 with sample diluent). Analytical Measurement Range is (approximate defined by curve) 62-500 mg/dl Reportable range 65-1000 mg/dl
MANUFACTURER ANALYTICAL MEASUREMENT RANGE (LINEARITY) FOR ACL	LABORATORY APPROVED CLINICAL REPORTABLE RANGE FOR ACL3000.
PT – 7.2-169 SECONDS (IN EXTENDED MODE)	PT'S GREATER THAN 100.0 SECONDS ARE REPORTED AS >100.0 SECONDS. (INR IS REPORTED AS >11.0) PT'S LESS THAN 7.2 SECONDS ARE REPORTED AS <7.2 SECONDS.
PTT – 9.2-249.0 SECONDS (IN EXTENDED MODE)	PTT'S GREATER THAN 150 SECONDS ARE REPORTED AS >150 SECONDS. PTT'S 9.2 SECONDS OR LESS ARE REPORTED AS < 9.2 SECONDS
FIBRINOGEN. 75-1000 MG/DL	A Fibrinogen < 75 mg/dl is reported as <75 mg/dl. A Fibrinogen >1000 mg/dl may be diluted 1.1 with IL Sample Diluent. The diluted result is then multiplied X 2 for the final value. Anything greater than 1600 mg/dl is reported as >1600 mg/dl. Analytical Range is 75-1000 mg/dl Reportable Range is 75-1600 mg/dl

ANALYTICAL MEASUREMENT RANGE (LINEARITY)
AND CLINICAL REPORTABLE RANGE FOR POINT OF CARE TESTING (WHOLE BLOOD GLUCOSE)

ANALYTE	ANALYTICAL MEASUREMENT RANGE (LINEARITY)	MANUAL DILUTION	CLINICAL REPORTABLE RANGE
WHOLE BLOOD GLUCOSE (ABBOTT Precision Xceed Pro™)	20-500 mg/dl	None	30-400 mg/dl **

LABORATORY STANDARD OPERATING PROCEDURES MANUAL	LABORATORY REPORTING RANGES AND REFERENCE RANGES
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**For any value outside of the reportable range, serum glucose will be added to be collected and performed, unless physician orders to not draw the patient and run the serum glucose.

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APPROVED BY. Martin F. Belli, M.D. DATE. 1-2002

REVISED BY. Kay Shaw, MT(ASCP)SBB DATE. 5-2002, 9-2002, 7-2003, 1-2004, 6-2004, 9-2005, 11-2005, 2-2006, 6-2006, 7, 2006, 4-2008 5-2008, 2-2009, 12-2009, 1-2010, 4-2010, 5-2010 6-2010, 8-2010, 9-2011, 1-2012

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See original policy in the laboratory for all documented annual reviews.

Reference.

1. CAP General Checklist, College of American Pathologists, Laboratory Accreditation Program, 1996.1 edition, 1996, pp.12-13.
2. CAP General Checklist with Commentaries, College of American Pathologists, Laboratory Accreditation Program, June 21, 2001, pp 28-29
3. Medical Laboratory Management and Supervision, Lionel A. Varnadoe, F. A. Davis and Company, 1996. p. 273

Laboratory Standard Operating Procedures Manual, Laboratory Collection Manual,