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Quality Assurance Instrument Comparison Procedure - Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. The purpose of this procedure is to evaluate the relationship between test results using different methodologies or instruments when the reagents/instruments are producing the same reportable result. The objective is to provide staff a written procedure for performing instrument comparisons.

II. POLICY:

A. If more than one instrument is used to test for a given analyte, the instruments must be checked against each other twice a year for correlation of patient results. This includes backup instruments which are not routinely set up for a particular analyte.

B. **STAT Lab only**: Instruments of the same manufacturer, loaded with the same lots of reagents, and evaluated by the same lots of controls are deemed comparable when controls fall within the current approved Quality Control (QC) ranges that apply to all instruments. Documentation of QC failures and corrective action are one and the same as the documentation of corrective action to restore instrument comparability. The procedures below apply where different test systems are used to test for a given analyte.

III. SPECIMEN COLLECTION AND HANDLING:

A. A minimum of 5 patient samples or patient sample pools across the Analytical Measurement Range (AMR) are used for the chemistry/immunoassay instruments.

B. Blood gas analyzers: Prepare five fresh sodium heparin whole blood samples and five fresh serum samples for instrument comparisons. Comparison results should cover a range of the AMR for each analyte.

IV. CALIBRATION:

All instruments should be calibrated and quality controlled as standard operating procedures indicate.

V. EQUIPMENT:

Automated Chemistry Line	Automated Chemistry Line	Radiometer ABL 825	STAT Lab
Architect i2000 #1	Architect c16000 #1	A	Architect ci4100 #1
Architect i2000 #2	Architect c16000 #2	B	
Architect i2000 #3	Architect c16000 #3	C	Architect ci4100 #2
Architect i2000 #4	Architect c16000 #4	D	
	Architect c8000 #1		
		Osmometer	**XN 3100**
		Stat Lab	36079
		Core Lab	36084

VI. PROCEDURE:

A. **For Architects**

1. Comparisons will be performed on a rotating basis twice a year.
2. Locate 5 samples with adequate volume or prepare 5 patient pools covering a range of the AMR.
3. Run samples in singlet on all instruments.
4. Print results from each instrument.

B. **For Radiometer**

1. Locate five fresh Heparin samples and five fresh serum samples (or prepare patient pools) covering a range of the AMR, and mix.
2. Analyze heparin samples on all blood gas analyzers and both XN3100's.
3. Analyze serum samples on all blood gas analyzers and Architects.
4. Log results onto the appropriate worksheet.

C. **For Osmometer**

1. Comparisons will be performed on a rotating basis twice a year.
2. Locate 5 serum and urine specimens with adequate volume covering a range of the AMR.
3. Run on both Osmometers.
4. Log results onto the appropriate worksheet.

VII. CALCULATIONS AND INTERPRETATIONS:

A. Use EP Evaluator to analyze the data collected on the worksheet. Analyze by multiple instrument comparison module or two-instrument comparison module.

B. The results are reviewed by the Technical Director. If the results are satisfactory, no further testing is necessary. If results exceed stated limits, follow up will be indicated by the clinical chemist.

C. Follow up for unsatisfactory comparisons, may include:

1. A detailed examination of Quality Control (QC) for the methods and a further comparison between

the instrument/methods will be performed. This initial comparison will consist of comparing the problem test(s) for 2 additional patient samples. If the comparison is within the acceptable limits, no further testing will be performed.

2. If one or both results fall outside the stated limits, additional testing will consist of comparing 10 patients' samples. If 80% of these comparisons are satisfactory, no further testing will be performed.
3. If there is significant difference, an additional 10 samples will be tested; regression analysis and paired t test will be performed to decide whether and how to make any instrument/method adjustments.

VIII. REFERENCES:

1. Skendzel LP, Barnett RN, Platt R. Medically Useful Criteria for Performance of Laboratory tests. American Journal of Clinical Pathology 1985; 83:200-205.
2. Fraser CG. The Application of Theoretical Goals Based on Biological Variation Data in Proficiency Testing. Arch Pathology Laboratory Medicine 1988; 112:404-415.
3. Cembrowski GS, Carey RN. Medical Usefulness Requirements of Analytical Systems. In: Laboratory Quality Management, ACSP 1989:80-99.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	11/5/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	11/5/2021
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr Laboratory	10/6/2021
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Lab Chemistry Best Practice Committee	Elizabeth Sykes: System Med Dir, Chemistry	10/6/2021
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