Clinical Performance of Reagent by Visual Analysis

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Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Albumin (Protein-Low)*
Technical Name	*Albumin (1)*
Clinical Study Report	*CTD 99-06 **
Date of Report	*June 1999*
Type of Study	*External, 2 clinical sites*
Test Solutions	*Clinical urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*734*
Comparative Method	*Nephelometric immunoassay*
Maximum Concentration considered "Negative"	*< 20 mg/dL albumin*
Analytical Sensitivity	*69 %*
Analytical Specificity	*92 %*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Bilirubin*
Technical Name	*Bilirubin (2)*
Clinical Study Report	*MPFO80685 **
Date of Report	*August 1985*
Type of Study	*In-house evaluation*
Test Solutions	*Contrived urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*144*
Comparative Method	*Urines at 4 fixed levels using assayed bilirubin stock standard*
Maximum Concentration considered "Negative"	*< 0.20 mg/dL bilirubin*
Analytical Sensitivity	*99 %*
Analytical Specificity	*89 %*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Blood*
Technical Name	*Occult Blood (9)*
Clinical Study Report	*Technical Review, QAD 90-36 **
Date of Report	*1990*
Type of Study	*In-house evaluation*
Test Solutions	*Contrived urines*
Number of Reagent Lots Used	*5*
Number of Results Obtained	*280*
Comparative Method	*Urines at 7 fixed levels using assayed blood stock standard*
Percent Agreement within ± one color block	*100 % at all 7 Levels*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Creatinine*	
Technical Name	*Creatinine (2)*	
Clinical Study Report	*CTD 99-06* *	
Date of Report	*June 1999*	
Type of Study	*External, 4 clinical sites*	
Test Solutions	*Clinical urines*	
Number of Reagent Lots Used	*2*	
Number of Results Obtained	*1585*	
Comparative Method	*Jaffe Reaction*	
Percent Agreement within ± one color block	*Color Block*	*% Agreement*
	10 mg/dL	*96*
	50 mg/dL	*97*
	100 mg/dL	*96*
	200 mg/dL	*99*
	300 mg/dL	*99*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Glucose*
Technical Name	*Quantitative Glucose (1)*
Clinical Study Report	*MPFO80685 **
Date of Report	*August 1985*
Type of Study	*External, 2 clinical sites*
Test Solutions	*Clinical urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*2577*
Comparative Method	*Hexokinase Assay*
Maximum Concentration considered "Negative"	*49.9 mg/dL glucose*
Analytical Sensitivity	*99%*
Analytical Specificity	*98%*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Ketone*
Technical Name	*Ketone (3)*
Clinical Study Report	*MPFO80685 **
Date of Report	*August 1985*
Type of Study	*External, 2 clinical sites*
Test Solutions	*Clinical urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*2576*
Comparative Method	*Sodium Nitroprusside Assay*
Maximum Concentration considered "Negative"	*9.9 mg/dL ketone*
Analytical Sensitivity	*92 %*
Analytical Specificity	*99 %*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Leukocyte*
Technical Name	*WBC (3)*
Clinical Study Report	*MPFO80685 **
Date of Report	*August 1985*
Type of Study	*External, 3 clinical sites*
Test Solutions	*Clinical urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*4824*
Comparative Method #1	*Chamber Count*
Maximum Concentration considered "Negative"	*< 10 whole blood cells / µL*
Analytical Sensitivity	*90 %*
Analytical Specificity	*71 %*
Comparative Method #2	*Sediment Count*
Maximum Concentration considered "Negative"	*< 5 whole blood cells / HPF*
Analytical Sensitivity	*91 %*
Analytical Specificity	*69 %*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Nitrite*
Technical Name	*Nitrite (4)*
Clinical Study Report	*MPFO80685 **
Date of Report	*August 1985*
Type of Study	*External, 1 clinical site*
Test Solutions	*Clinical urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*304*
Comparative Method	*Sulfanilamide-HTBQ assay*
Maximum Concentration considered "Negative"	*0.03 mg/dL nitrite*
Analytical Sensitivity	*88 %*
Analytical Specificity	*90 %*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*pH*	
Technical Name	*pH (1)*	
Clinical Study Report	*MPFO80685 **	
Date of Report	*August 1985*	
Type of Study	*External, 2 clinical sites*	
Test Solutions	*Clinical urines*	
Number of Reagent Lots Used	*2*	
Number of Results Obtained	*2584*	
Comparative Method	*pH Meter*	
Percent Agreement within ± one color block	*Color Block*	*% Agreement*
	5.0 pH	*99*
	6.0 pH	*99*
	6.5 pH	*90*
	7.0 pH	*89*
	7.5 pH	*98*
	8.0 pH	*89*
	8.5 pH	*100*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent	*Protein*
Technical Name and Suffix	*Protein (4)*
Clinical Study Report	*CTD 94-04 **
Date of Report	*May 1994*
Type of Study	*External, 4 clinical sites*
Test Solutions	*Clinical urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*390*
Comparative Method #1	*human serum albumin assay*
Maximum Concentration considered "Negative"	*< 4.0 mg/dL albumin*
Analytical Sensitivity	*99.5 %*
Analytical Specificity	*67.4 %*
Comparative Method #2	*total protein assay*
Maximum Concentration considered "Negative"	*< 15 mg/dL total protein*
Analytical Sensitivity	*99.4 %*
Analytical Specificity	*72.4 %*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent	*Protein (Protein-High)*
Technical Name and Suffix	*Protein (4)*
Clinical Study Report	*CTD 99-06 **
Date of Report	*June 1999*
Type of Study	*External, 2 clinical sites*
Test Solutions	*Clinical urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*1711*
Comparative Method #1	*total protein (TP) assay* ***and*** *human serum albumin (HSA) assay*
Maximum Concentration considered "Negative"	*Dual criteria: < 25 mg/dL TP* ***and*** *< 10 mg/dL HSA*
Analytical Sensitivity	*93 %*
Analytical Specificity	*91 %*
Comparative Method #2	*total protein assay*
Maximum Concentration considered "Negative"	*<25 mg/dL total protein*
Analytical Sensitivity	*92 %*
Analytical Specificity	*85 %*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Specific Gravity*
Technical Name	*Specific Gravity (3)*
Clinical Study Report	*MPFO80685 **
Date of Report	*August 1985*
Type of Study	*External, 2 clinical sites*
Test Solutions	*Clinical urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*2558*
Comparative Method	*Total Solids Meter*

Percent Agreement within ± one color block	*Color Block*	*% Agreement*
	1.005	*98*
	1.010	*77*
	1.015	*82*
	1.020	*71*
	1.025	*79*
	1.030	*59*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Urobilinogen*
Technical Name	*Urobilinogen (4)*
Clinical Study Report	*Technical Review S85-40 **
Date of Report	*1985*
Type of Study	*In-house evaluation*
Test Solutions	*Clinical urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*216*
Comparative Method #1	*Watson's Aldehyde Assay*
Maximum Concentration considered "Negative"	*< 2.0 mg/dL urobilinogen*
Analytical Sensitivity	*47 %*
Analytical Specificity	*98 %*
Comparative Method #2	*Uro3 test pad*
Maximum Concentration considered "Negative"	*< 2.0 mg/dL urobilinogen*
Analytical Sensitivity	*100 %*
Analytical Specificity	*100 %*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana

Clinical Performance of Reagent by Visual Analysis

Reagent Pad	*Urobilinogen*
Technical Name	*Urobilinogen (4)*
Clinical Study Report	*MPFO80685 **
Date of Report	*August 1985*
Type of Study (#1)	*External, 1 clinical site*
Test Solutions	*Clinical Urines*
Number of Reagent Lots Used	*2*
Number of Results Obtained	*2119*
Comparative Method	*Uro3 test pad*
Maximum Concentration considered "Negative"	*< 2.0 mg/dL urobilinogen*
Analytical Sensitivity	*84 %*
Analytical Specificity	*100 %*
Type of Study (#2)	*In-house Evaluation*
Test Solutions	*Contrived urines at 4 fixed levels using assayed urobilinogen stock*
Number of Reagent Lots Used	*3*
Number of Results Obtained	*144*
Comparative Method	*Uro3 test pad*
Maximum Concentration considered "Negative"	*< 2.0 mg/dL urobilinogen*
Percent Agreement	*Normal: 100%* *Abnormal: 100%*

* Located in Central File, Clinical Trials Department, Elkhart, Indiana