


AXIS-SHIELD CLINICAL CHEMISTRY ANTI-CCP

APPLICATION GUIDE FOR:

Horiba ABX Pentra 400

Test Name	ACCP	Channel	999	Code	ACCP	Local code	ACCP
		<input checked="" type="checkbox"/> Enable		Modified on	07/13/2016 11:21		

General Parameters

Characteristics		<input type="checkbox"/> Pre-dilution	
Sample Type	Serum / Plasma	Diluent Name	--
Number of Reagents	Reagent 3	Factor	--
Reagent		Incubation time (in cycles)	--
Reagent Short Name	ACCP	<input type="checkbox"/> Linearity (U/mL)	
Reagent Number	901	Low Limit	High Limit
On Board Stability (days)	--	Correlation Slope	Intercept
<input type="checkbox"/> Cassette		1.00000	0.00000

<input type="checkbox"/> Delta Check		
Delta Check Validity	Absolute Variation	Relative Variation
--	--	--

Automatic Rerun			
<input type="checkbox"/> Post Dilution	--		
<input type="checkbox"/> Post Concentration	--		

Reference Range (U/mL)			
<input type="checkbox"/> Low Check	Man / Default	Woman	Child
<input type="checkbox"/> High Check	--	--	--

Result			
Unit	U/mL		
Decimal Position	1		
<input type="checkbox"/> Manual Patient Validation			

Rerun range (U/mL)			
<input type="checkbox"/> Low Check	Man / Default	Woman	Child
<input type="checkbox"/> High Check	--	--	--

Calibration Parameters

<input type="checkbox"/> Pre-dilution		Checks	
Type	Calibrator Diluent	<input type="checkbox"/> Reagent Limit Absorbance Check	
Factor 1	Factor 2	Reagent Range Low	--
Factor 3	Factor 4	Reagent Range High	--
Factor 5	Factor 6	<input type="checkbox"/> Reagent Blank Limit Absorbance Check	
Factor 7	Factor 8	Blank Range - Low Limit	--
--	--	Blank Range - High Limit	--

<input type="checkbox"/> Control required		Validity backup	
<input type="checkbox"/> Control used 1	--	<input type="checkbox"/> Backup time frame without calibration required	
<input type="checkbox"/> Control used 2	--	Interval	0
<input type="checkbox"/> Control used 3	--	Time Unit	Days

Calibration		Validity		Factor calibration	
Calibration Mode	Linear interpolation	<input checked="" type="checkbox"/> On Request		<input type="checkbox"/> Low Limit Check	
Level	5	<input type="checkbox"/> Time Validity		<input type="checkbox"/> High Limit Check	
Calibration Factor	--	Interval	--	<input type="checkbox"/> Relative Variation Check	
Run(s)	3	Time Unit	--		
Dev_Rep (%)	--				
Dev_C (%)	--				
Calibrator Used	ccp1				

Analysis parameters

<input type="checkbox"/> Cleaner		Wavelength (nm)		Blank	
Cleaner Solution	<input type="checkbox"/> H2O	Primary Wavelength	700	<input checked="" type="checkbox"/> Reagent Blank	
<input type="checkbox"/> Before	<input type="checkbox"/> After	Secondary Wavelength	--	Diluent	H2O

Analysis Sequence					
Cycle	Reagent Needle	Volume (µL)	Sample Needle	Volume (µL)	H2O Vol (µL)
1	R1	200.0	SAMPLE	7.0	--
10	R2	50.0	--	--	--
28	--	--	R3	2.0	--
--	--	--	--	--	--

Mixing Speed
100

Test Name ACCP Channel 999 Code ACCP Local code ACCP
 Enable Modified on 07/13/2016 11:21

Calculation parameters

Correlation Factor		Reaction Direction	
Slope	1.00000	<input type="checkbox"/> Reaction Direction Check	Reaction Direction Increase
Intercept	0.00000		

<input type="checkbox"/> Sample Limit Check		<input type="checkbox"/> Antigen Excess Check	
Sample limit (Δ O.D.)	-	Antigen Excess Limit (%)	-
Sample Limit Cycle	-	Antigen Excess Point	-

<input checked="" type="checkbox"/> Definition Step A			
Calculation Type		End Point	
First Reading		Last Reading	
Cycle	11	Cycle	28
<input type="checkbox"/> Reaction Limit Check		Reaction Limit Absorbance	
		Cycle	
OD deviation check			
<input type="checkbox"/> Linear Regression		<input type="checkbox"/> First point	<input type="checkbox"/> Last point
r2 threshold	SD	First point threshold	SD Factor

<input type="checkbox"/> Definition Step B			
Calculation Type		End Point	
First Reading	-	Last Reading	-
Cycle	-	Cycle	-
<input type="checkbox"/> Reaction Limit Check		Reaction Limit Absorbance	
		Cycle	
OD deviation check			
<input type="checkbox"/> Linear Regression		<input type="checkbox"/> First point	<input type="checkbox"/> Last point
r2 threshold	SD	First point threshold	SD Factor

<input type="checkbox"/> Definition Step C			
Calculation Type		End Point	
First Reading	-	Last Reading	-
Cycle	-	Cycle	-
<input type="checkbox"/> Reaction Limit Check		Reaction Limit Absorbance	
		Cycle	
OD deviation check			
<input type="checkbox"/> Linear Regression		<input type="checkbox"/> First point	<input type="checkbox"/> Last point
r2 threshold	SD	First point threshold	SD Factor

<input type="checkbox"/> Definition Step D			
Calculation Type		End Point	
First Reading	-	Last Reading	-
Cycle	-	Cycle	-
<input type="checkbox"/> Reaction Limit Check		Reaction Limit Absorbance	
		Cycle	
OD deviation check			
<input type="checkbox"/> Linear Regression		<input type="checkbox"/> First point	<input type="checkbox"/> Last point
r2 threshold	SD	First point threshold	SD Factor

Formula	-
---------	---

Units parameters

Unit:	Conversion Factor :
U/mL	1.000000
-	-
-	-

Unit:	Conversion Factor :
-	-
-	-
-	-

Materials provided:

Axis-Shield Clinical Chemistry Anti-CCP Reagent IFU
Reagent 1 (FHCCP130)
Reagent 2 (FHCCP110)

Materials required but not provided:

Appropriate system-specific bottles (1 to 15 mL)
Note: For application on the ABX Pentra 400, an additional Reagent 3 needs to be prepared. See below:

System-specific handling requirements:

Reagent / Part No.	mL required for 50 tests	Formulae to calculate mL required for X*tests
R1/FHCCP130	Decant 15mL * R1 into system-specific bottle	Vol required (mL) = (no. of tests x 0.2) + 5mL
R2/FHCCP110	Decant 5mL * R2 into system-specific bottle	Vol required (mL) = (no. of test x 0.05) + 2.5mL
R3/FHCCP130	Decant 1mL * R1 into system-specific bottle	Vol required (mL) = (no. of test x 0.002) + 0.9mL

** user defined parameters*

Calibration Curve Frequency:

Calibration curve stability is up to 5 days. Recalibration is also recommended after a change in reagent lot, if a control reads out-of-range or as required following quality control procedures.

Reagent Stability

On-board: Do not store reagents on-board the ABX Pentra 400.

In-use: Stability in system-specific bottles has not been verified. Any unused reagents in original packaging must be returned to refrigerated storage after use.