## Ortho Clinical Diagnostics

Because Every Test Is A Life™

PRODUCT NAME	ORTHO® HCV 3.0 ELISA Test System	Bio Rad GS HBsAg 3.0 EIA	Bio Rad GS HIV-1/HIV-2 PLUS 0
Product Codes	6195566, 6195567	32591, 25258	32588, 25256
Remove from 2-8°C, 30 min Before Use	All Reagents	All except Conj. Conc.	All except Conj. Conc.
Assay ID	DD	BK	AJ
Open Plate (Pouch) stable w/desiccant	42 days	Plate Package	Plate Package
BLANK WELL Y/N	Yes - 1A	No	No
CONTROLS Per Plate	3-Neg 2-Pos	3-Neg 2-Low Pos 2-Pos	3-Neg 1-Pos 1, 1-Pos 2, 1-Pos 0
External Run Control Type (Neg/ Pos) – required	Neg	Neg	Neg
SPECIMEN DILUENT Volume	200 µL (except 1A)	None	25 µL
CONTROL/SAMPLE Volume	10 µL	100 µL	75 µL
1st INCUBATION TIME (min)	60 ±5	60 ±5	60 ±5
1st INCUBATION TEMP °C	37 ±1	37 ±1	37 ±2
WASH BUFFER Type	20X	30X	30X
WASH Sol. Exp. (Rm Temp)	30 days	4 weeks	4 weeks
CONJUGATE - Prep?	Stable - No prep	Prep Required	Prep Required
CONJUGATE STABILITY (how long can it be used)	N/A	8 hrs	8 hrs
CONJUGATE Volume	200 µL (except 1A)	100 µL	100 µL
2 <sup>nd</sup> INCUBATION TIME (min)	60 ±5	60 ±5	30 ±5
2 <sup>nd</sup> INCUBATION TEMP °C	37 ±1	37 ±1	37 ±2
SUBSTRATE Volume	200 µL (including 1A)	100 µL	100 µL
SUBSTRATE STABILITY-dark	8 hrs	8 hrs	8 hrs
Is it a TMB SUBSTRATE? y/n	No	Yes	Yes
IF YES – what is unique about the reagent container?	N/A	Discard after each use	Discard after use
3rd INCUBATION TIME (min)	30 ±1	30 ±3	30 ±5
3 <sup>rd</sup> INCUBATION TEMP °C	15 - 30	15 - 30	18 - 30
Stopping Solution Used	4N	1N	1N
Stopping Solution Volume	50 µL	100 µL	100 µL

<sup>\*</sup>EnzAbody Concentrate - Pipet 4.0 ml EnzAbody Diluent into 1 vial of lyophilized EnzAbody Concentrate at least 30 min prior to use, expires in 5 weeks when stored at 2-8 °C.

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SAMPLES				
Ambient Shipping	OK up to 7 days	OK up to 7 days	OK up to 7 days	
Specimen Storage (includes transit if not frozen)	2-8 °C up to 10 days	2-8 °C up to 7 days	2-8 °C up to 7 days	
Freeze limitations	4 weeks/5 cycles	5 cycles	5 cycles	
Preferred attributes	Clear, non-hemolyzed	N/A	N/A	
Centrifugation	Visible particulates	Visible particulates	Visible particulates	
Cadaveric Claim	Yes	Yes	Yes	

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