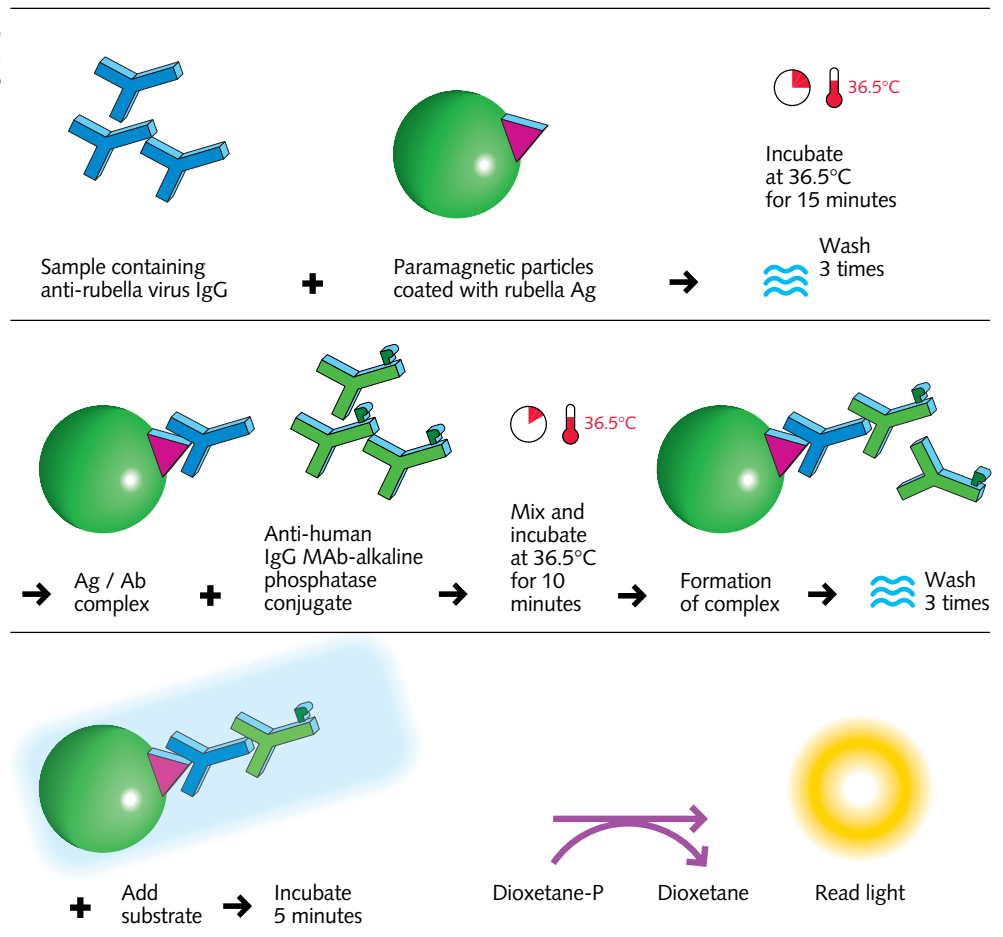


**Access**  
Infectious  
Disease

# Rubella IgG

- *Highly specific and sensitive*
- *Immunity threshold: 15 IU/mL*
- *Reportable range of up to 500 IU/mL*
- *Standardized against the WHO Reference Preparation (2nd I.S.P.)*
- *Calibration stability: 28 days*
- *Two level QC controls*
- *Time to first results: 35 minutes*

**2 step  
sandwich  
technique**



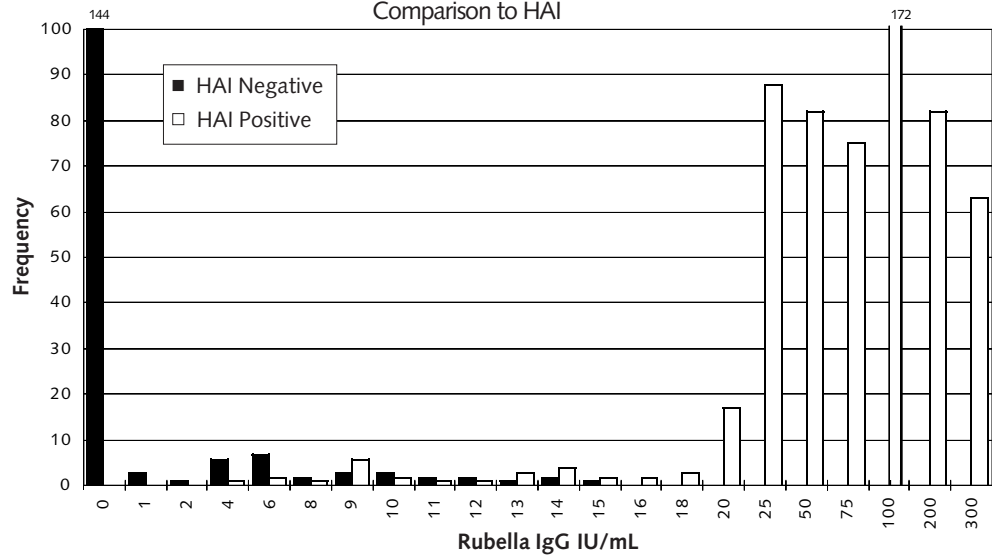
**Signal produced is directly proportional to the anti-rubella virus IgG concentration in the sample.**

## Performance Comparison to hemagglutination inhibition (HAI) method

### Access® vs. HAI

	N	HAI ACCESS®	+	+	+	-	-	-	Relative Sensitivity	95% Conf. Int.	Relative Specificity	95% Conf. Int.
			+	-	EQ	EQ	+	-				
Site 1	385	Frozen	280	0	1	10	1	93	100%	98.7-100	99%	94.2-100
Site 1	25	Fresh	22	0	0	0	0	3	100%	84.6-100	100%	29.2-100
Site 2	349	Frozen	264	10	10	0	0	65	96%	93.4-98.2	100%	94.5-100
Site 2	25	Fresh	20	0	0	0	0	5	100%	83.2-100	100%	47.8-100
TOTAL	784		586	10	11	10	1	166	98%	96.9-99.2	99%	96.7-100

Clinical Study (2 Sites) Sample Distribution Comparison to HAI



### Characteristics

Sample Type/Size	Serum/20 µL
Time to 1st Result	35 minutes
Calibrator Levels	0, 10, 25, 50, 200, and 500 IU/mL
Interpretation	< 10 IU/mL non-reactive; ≥10 - <15 IU/mL equivocal; ≥ 15 IU/mL reactive
Open Pack Stability	28 days
Calibration Stability	28 days
Precision	< 15%

### Ordering Information

Access® Rubella IgG - 2 packs of 50 tests/pack	34430
Access® Rubella IgG Calibrators - 6 vials of 1 mL/vial	34435
Access® Rubella IgG QC - 2 levels, 3 vials/level of 2.6 mL/vial	34439

