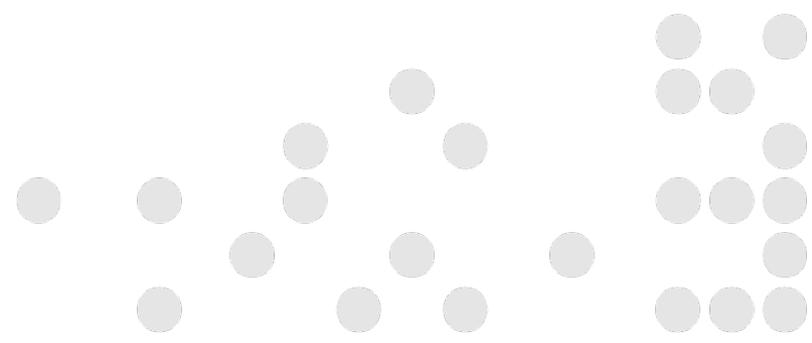


Ortho Clinical Diagnostics

**Throughput and
Single Sample Turnaround Time for
ORTHO VISION™ and ORTHO VISION
Max Analyzer**



Throughput and Single Sample Turnaround Time

ORTHO VISION™ Platform (Biovue)

Ortho Definition Tput and TAT

- **Throughput**

Steady state throughput is defined as the period of time when the analyzer, after receiving an uninterrupted supply of samples, is at the maximum, unchanging throughput. This is estimated to be at approximately 1.5 hours after start, defined as the ramp up time, and lasts until the last sample has started, defined as the ramp down time. Steady state throughput is calculated using a rolling average during this period.

- **Turnaround Time (Single Sample)**

Turn-around-time is defined as the time to complete tests and post results on the instrument based on the time of load of sample to the system to the result time for a test or a complete profile of tests to post results and is established on the basis of a single sample loaded to the instrument with no other testing being executed or in process on the instrument.

Profile	Cassette	Ortho Vision™		Ortho Vision™ Max		
		TPT (results/hr)	TAT (min)	TPT (results/hr)	TAT (min)	
Grp/Rh (0.8% Rev2)	ABO-Rh/Rev Grouping (00)	22	10	NT	NT	
Screen (0.8% 3Cell)	Anti-AHG (22)		22			
Grp/Rh (0.8% Rev2)	ABO-Rh/Rev Grouping (00)	22	10	40	7.5	
Screen (0.8% 3Cell)	Anti-IgG (33)		22		22	
Grp/Rh (0.8% Rev2)	ABO-Rh Grouping (44)#	24	12	38	11	
Screen (0.8% 3Cell)	Reverse (66)		23		22	
	Anti-IgG (33)					
Grp/Rh (0.8% Rev3)	ABO-Rh Grouping (44)#	20	12	36	11	
Screen (0.8% 3Cell)	Reverse (66)		23		22	
	Anti-IgG (33)					
Grp/Rh (0.8% Rev3)	ABO-Rh Grouping (44)#	20	12	NT	NT	
Screen (0.8% 3Cell)	Reverse (66)		22			
	Anti-AHG (22)					
Grp/Rh (0.8% Rev4)	ABO-Rh Grouping (44)#	NT	NT	32	11	
Screen (0.8% 3Cell)	Reverse (66)				22	
	Anti-IgG (33)					
Grp/Rh (0.8% Rev2)	ABO-Rh/RevGrouping (00)	15	10	32	8	
Grp Confirm (new susp)	ABD (10)		10		8	
Screen (0.8% 3Cell)	Anti-AHG (22)		23		22	
Grp Confirm	ABD (10)	29	8	48	8	
Screen (0.8% 3Cell)	Anti-IgG (33)		23		22	
Grp/Rh (0.8% Rev2)	ABO-Rh Grouping (44)#	24	12	31	8	
Rh/K Pheno	Reverse (66) + Rh/K (77)		12		11	
Grp/Rh (0.8% Rev2)	ABO-Rh Grouping (44)#	16 - 1.x	12	25 - IgG	8	
Rh/K Pheno	Reverse (66) + Rh/K (77)	20 - 2.x	12		25 - Poly	12
Screen (3Cell)	Anti-IgG (33)		22			21

Profile	Cassette	Ortho Vision™		Ortho Vision™ Max	
		TPT (results/hr)	TAT (min)	TPT (results/hr)	TAT (min)
Grp/Rh (0.8% Rev2)	ABO-Rh/RevGrouping (00)	28	8	46	7
Grp/Rh (0.8% Rev2)	ABO-Rh Grouping (44)# Reverse (66)	25	12	45	7
Donor/Patient ABD Confirm	ABD (10)	48	6	82	6
Screen (0.8% 3Cell)	Anti-IgG (33)	53	22	66	22
Rh/K Pheno	Rh/K (77)	42	11	75	11
Major XM	Anti-AHG (22) or Anti-IgG (33)	32 XM 16 Patients 2 unit XM	24 1 patient 2 unit XM	20 patient 2 unit XM	23 1 patient 2 unit XM
Grp/Rh (3% Rev2)	ABO-Rh/Reverse Grouping (00)		11	TBD	TBD
Screen Poly + Neut (3% FT & UnT)	Neutral (88) Poly AHG (22)	13	20		
Grp/Rh (3% Rev2)	ABO-Rh/Reverse Grouping (00)		10	TBD	TBD
Screen Poly/Neut (3% FT & UnT)	PolyAHG-Neutral (55)	12	20		
Screen Poly + Neut (3% FT & UnT)	PolyAHG-Neutral (55)	28	19	40	17
Grp/Rh (3% Rev2) Bromelin 3% (2cell +Dia)	ABO-Rh/Reverse Grouping (00) PolyAHG-Neutral (55)	12	TBD	24	TBD
Grp/Rh/K (0.8% Rev4) Rh/K Pheno Screen (0.8% 3Cell) w/Autocontrol	ABO-Rh Grouping (44) Reverse (66) Rh/K (77) Poly (22)	8	TBD	16	TBD
Antibody Identification Panel (0.8% Ficin, Tr & Untr)	Polyspecific (22) Neutral (88)	5	TNP	TBD	TNP
IAT Titration (0.8% cell in IgG)	Anti-AHG (22) or Anti-IgG (33)	8	TBD	TBD	TBD

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TPT and TAT Criteria For Data

- **Throughput is based on a specific profile test executed over several hours of testing to establish steady state and then calculated on a rolling hourly average.**
- **Turn-around-time is established on the basis of a single sample profile type loaded to the instrument with no other testing being executed or in process on the instrument.**
- **The data presented here is based on testing performed with one instrument.**
- **Operator results may vary dependent on loading sequence, the loading sequence followed a specific process for the generation of TPT and TAT data**
- **TAT is listed as a total time for a profile of a single test. If multiple TAT are listed in stacked format the first time for the forward & reverse grouping and the final time for the entire profile**
- **All ORTHO VISION™ testing completed on 1.x SW except France full G&S conducted on 2.x. ORTHO VISION™ Max conducted on 2.x SW (see chart that lists both results)**

- **The following apply to each page of data:**

NT - Test will not be executed as results expected to be equivalent to the IgG test. Based on French profile test using IgG and Poly AHG test

TBD – Testing to create data or analysis of available data not yet complete

TNP - Testing not planned