



Sample Test Report



Order ID 619603
 Provider Exagen Inc.

Specimen		Patient	
Collected	12/31/2020		Patient, Example
Received	01/01/2021	Gender - DOB	Female - 01/12/1990
Test Order		Identifier Received	
Created	01/01/2021	Exagen ID	707382
Reported	01/02/2021		

AVISE SLE Monitor Test Report

	Value	Interpretation	Reference Range
Complement Component			
+ EC4d - Erythrocyte-bound C4d	20 Net MFI	POSITIVE	FACS: <15 - Negative ≥15 - Positive
Complement C3	105 mg/dL	Normal	Turbidimetry: 81 - 157 - Normal
Complement C4	25 mg/dL	Normal	Turbidimetry: 13 - 39 - Normal
Antibody Component			
+ Anti-dsDNA IgG	60 IU/mL	POSITIVE	CIA: <27 - Negative 27 - 35 - Indeterminate ≥36 - Positive
+ Anti-C1q IgG	30 Units	POSITIVE	ELISA: <20 - Negative ≥20 - Positive
Thrombosis-associated Marker			
+ PC4d - Platelet-bound C4d		POSITIVE - confirmation required with new specimen	
Therapy Monitoring			
Hydroxychloroquine	800 ng/mL	Sub-therapeutic	

Analyte Descriptions

EC4d

Erythrocyte-bound C4d (EC4d) measured by flow cytometry has been shown to significantly correlate with disease activity as measured by clinical SELENA-SLEDAI [1,2]. Furthermore, reductions in EC4d levels have been shown to correlate with improvements in SF-36 score and BILAG-2004 index [2].

Complement C3/C4

Normalization of complement C3 and C4 proteins has been shown to correlate with disease improvements in SLE [1-3].

Anti-dsDNA IgG

Anti-dsDNA is quantified using a bead-based chemiluminescence immunoassay method. Relative to other methods, values produced by this method have superior correlation with disease activity [3,4].

Anti-C1q IgG

Autoantibodies to C1q have been shown to significantly correlate with clinical SELENA-SLEDAI values and are superior to 3 other biomarkers in their association with lupus nephritis and proteinuria [2,3,5].

PC4d

Elevated (positive) platelet-bound C4d (PC4d) levels have been associated with a history of thrombosis in lupus [6,7,8]. Patients with persistent elevated PC4d have been shown to have significant association with thrombosis [6,9].

Test Method Description

The disease monitoring panel consists of C4d bound to erythrocytes or platelets (determined by flow cytometry), soluble complement C3c and C4 proteins (determined by immunoturbidimetry), and SLE auto-antibodies (anti-double stranded DNA and anti-C1q IgG, all determined by immunoassays). Changes in EC4d, anti-dsDNA, anti-C1q and complement proteins have been shown to correlate with change in SLE disease activity, as defined by clinical SELENA-SLEDAI, BILAG index score and proteinuria [1-3].

References

- Kao A, et al. Erythrocyte C3d and C4d for Monitoring Disease Activity in Systemic Lupus Erythematosus. Arthritis and Rheumatism 62[3], 837-844. 2010
- Buyon J, et al. Reduction in Erythrocyte Bound Complement Activation Products and Titers of Anti-C1q antibodies associate with clinical improvement in systemic lupus erythematosus. Lupus Science & Medicine 2016
- Merrill J, et al. Erythrocyte-bound C4d in combination with complement and autoantibody status for the monitoring of SLE. Lupus Sci Med. 2018;5(1):e000263
- Mahler M, et al. Performance Characteristics of Different Anti-Double-Stranded DNA Antibody Assays in the Monitoring of Systemic Lupus Erythematosus. J Immunol Res. 2017;2017:1720902.
- Orbai A, et al. Anti-C1q Antibodies in Systemic Lupus Erythematosus. Lupus. 2015 January; 24(1): 42-49
- Kao A, et al. Relation of platelet C4d with all-cause mortality and ischemic stroke in patients with systemic lupus erythematosus. Transl Stroke Res. 2014 Aug;5(4):510-8
- Petri M, et al. Complement C4d Split Products in Combination with Lupus Anticoagulant and Low Complement Associate with Thrombosis in Systemic Lupus Erythematosus [abstract]. Arthritis Rheumatol. 2018; 70 (suppl 10).
- Lood C et al. Platelet activation and anti-phospholipid antibodies collaborate in the activation of the complement system on platelets in systemic lupus erythematosus. PLoS One. 2014; doi: 10.1371/journal.pone.0099386. eCollection 2014.
- Data on file - Exagen Diagnostics, Inc.



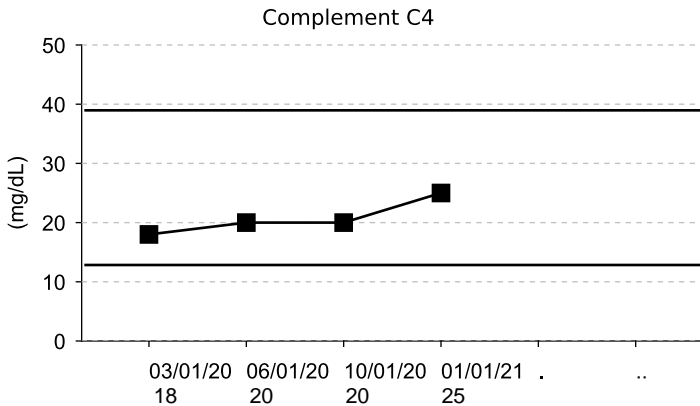
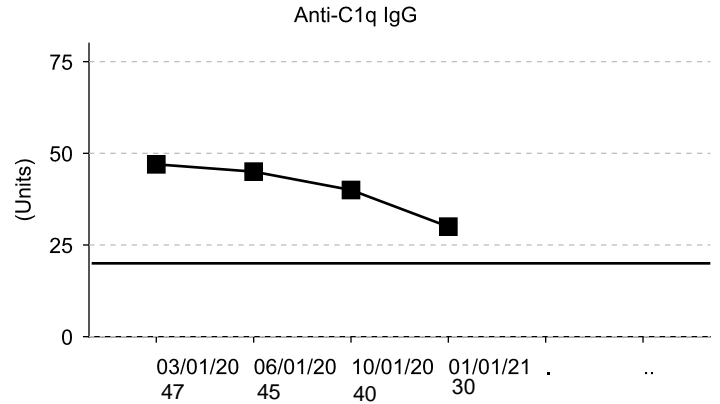
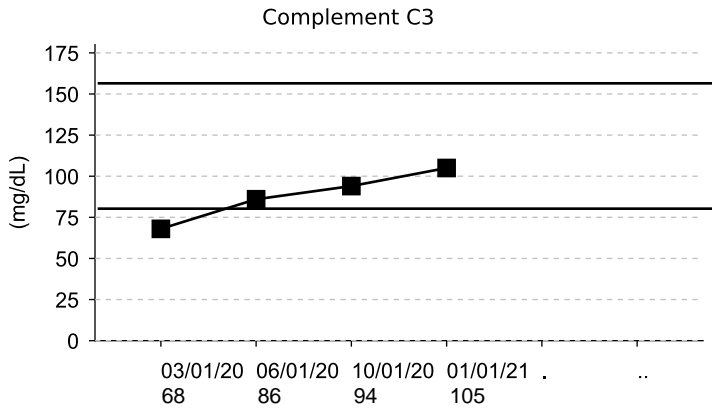
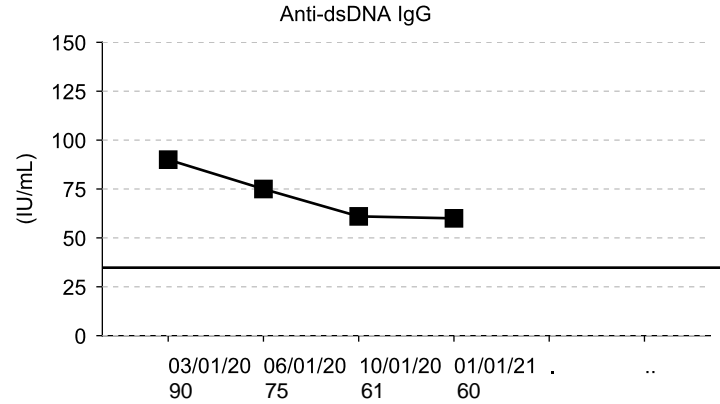
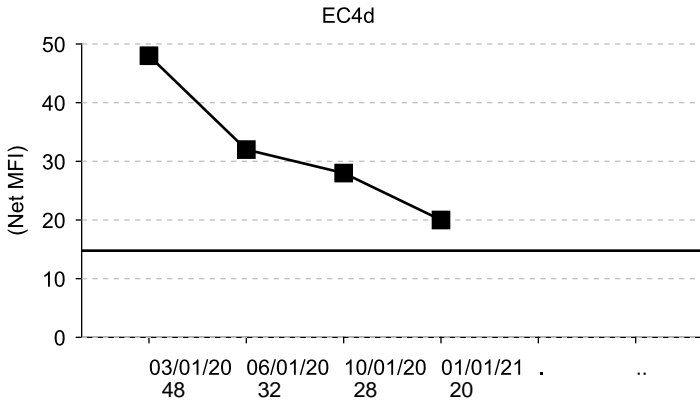
Order ID 619603
 Provider Exagen Inc.

Specimen
 Collected 12/31/2020
 Received 01/01/2021
Test Order
 Created 01/01/2021
 Reported 01/02/2021

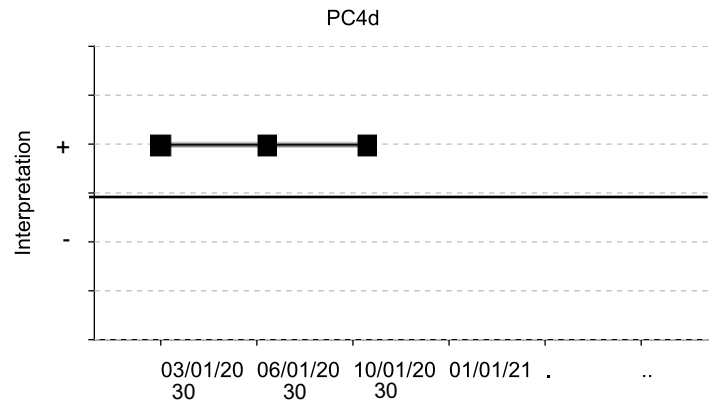
Patient
Patient, Example
 Gender - DOB Female - 01/12/1990
 Identifier Received
 Exagen ID 707382

Complement Component

Antibody Component



Thrombosis-associated Marker



1261 Liberty Way, Vista CA 92081
 CLIA# 05D1075048
 CAP# 7201051 | NYSDOH PFI# 8369

Laboratory Directors:
 Richard Safrin, MD
 R. Harper Summers, MD

Provider Relations: 888.452.1522

AVISE and the AVISE and Exagen logos are registered trademarks of Exagen Inc. ©2021 All Rights Reserved



Order ID 619603
 Provider Exagen Inc.

Specimen
 Collected 12/31/2020
 Received 01/01/2021
Test Order
 Created 01/01/2021
 Reported 01/02/2021

Patient
Patient, Example
 Gender - DOB Female - 01/12/1990
 Identifier Received
 Exagen ID 707382

AVISE MONITOR HEMATOLOGY

Test Name	Result	Unit	Flags	Reference Range
WBC	5.2	x10 ³ /μL		3.9 - 9.8
RBC	4.3	x10 ⁶ /μL		4.0 - 5.6
HGB	13.1	g/dL		12.1 - 17.4
HCT	39.5	%		37.1 - 49.4
MCV	91.8	fL		76.4 - 105.4
MCH	30.5	pg		25.2 - 36.6
MCHC	33.2	g/dL		32.2 - 35.7
RDW	14.1	%		10.7 - 17.5
MPV	9.5	fL		7.1 - 10.0
PLT	235.0	x10 ³ /μL		146 - 438
NEU	1.9	x10 ³ /μL		1.7 - 6.8
LYM	2.8	x10 ³ /μL		0.7 - 3.5
MON	0.5	x10 ³ /μL		0.1 - 0.8
EOS	0.1	x10 ³ /μL		0.0 - 0.4
BAS	0.0	x10 ³ /μL		0.0 - 0.2
NEU%	36.5	%		
LYM%	53.2	%		
MON%	9.0	%		
EOS%	1.1	%		
BAS%	0.2	%		

DIFF TYPE: Automated

Result Flags: L=Low, H=High, CL=Critical low, CH=Critical High

AVISE MONITOR CHEMISTRY

Test Name	Result	Unit	Flags	Reference Range
Creatinine	0.90	mg/dL		0.5 - 0.9 Women 0.7 - 1.2 Men
CRP	1.5	mg/L		1 - 5

Test Method Description

CBCs were generated on CELL-DYN Emerald 22 AL (Abbott), a quantitative multi-parameter automated hematology analyzer designed for IVD enumeration of WBC, LYM%, LYM #, MON%, MON #, NEU%, NEU #, EOS%, EOS #, BAS%, BAS #, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV from K2EDTA anti-coagulated whole blood. Creatinine and CRP were measured on Pentra 400C analyzer (HORIBA) from SST serum.

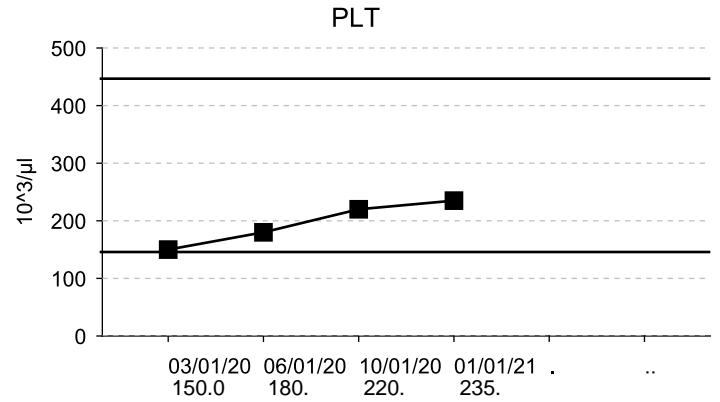
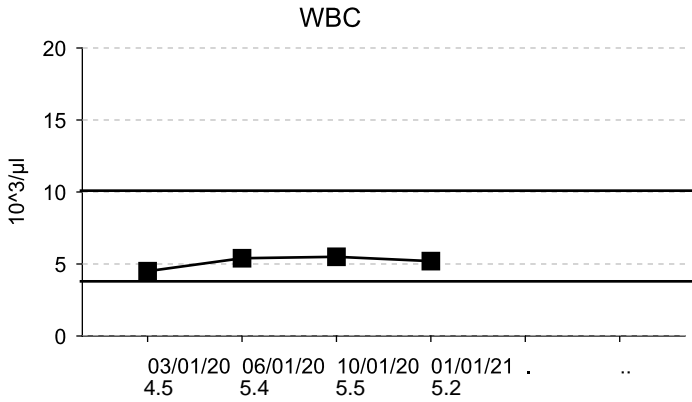


Order ID 619603
 Provider Exagen Inc.

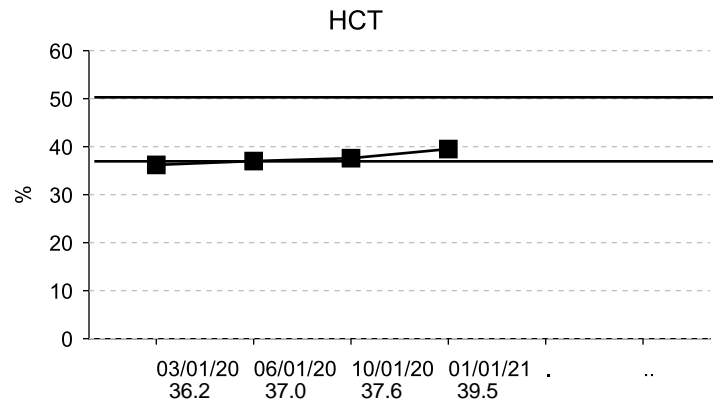
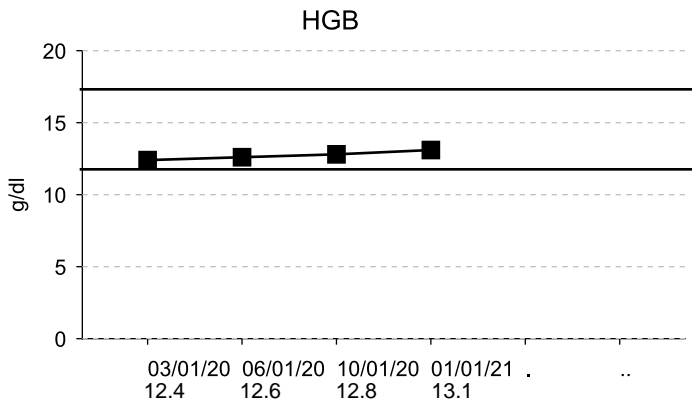
Specimen
 Collected 12/31/2020
 Received 01/01/2021
Test Order
 Created 01/01/2021
 Reported 01/02/2021

Patient
Patient, Example
 Gender - DOB Female - 01/12/1990
 Identifier Received
 Exagen ID 707382

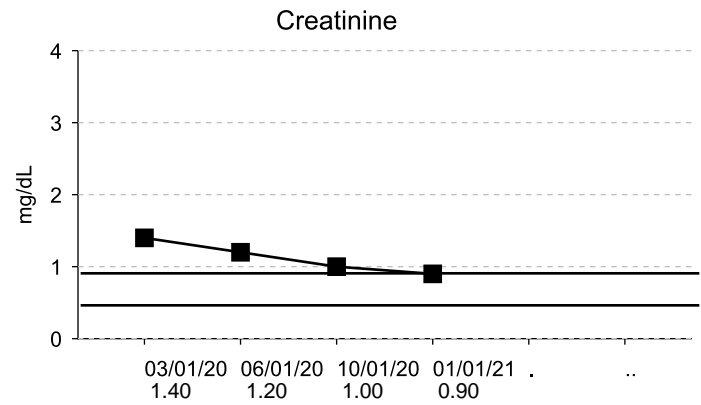
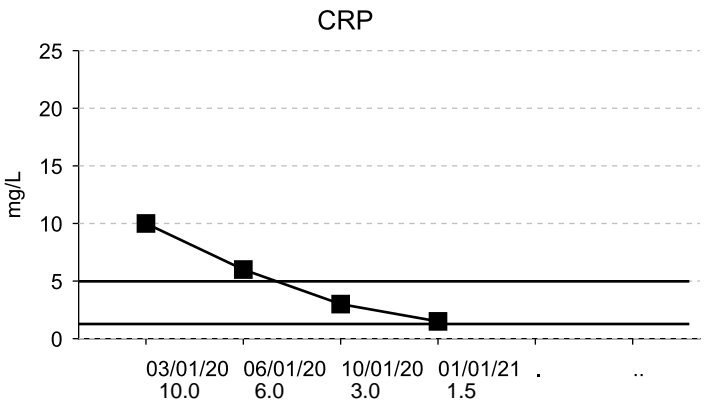
Hematology



Hematology



Chemistry



1261 Liberty Way, Vista CA 92081
 CLIA# 05D1075048
 CAP# 7201051 | NYSDOH PFI# 8369

Laboratory Directors:
 Richard Safrin, MD
 R. Harper Summers, MD

Provider Relations: 888.452.1522

AVISE and the AVISE and Exagen logos are registered trademarks of Exagen Inc. ©2021 All Rights Reserved



Order ID 619603
 Provider Exagen Inc.

Specimen
 Collected 12/31/2020
 Received 01/01/2021
Test Order
 Created 01/01/2021
 Reported 01/02/2021

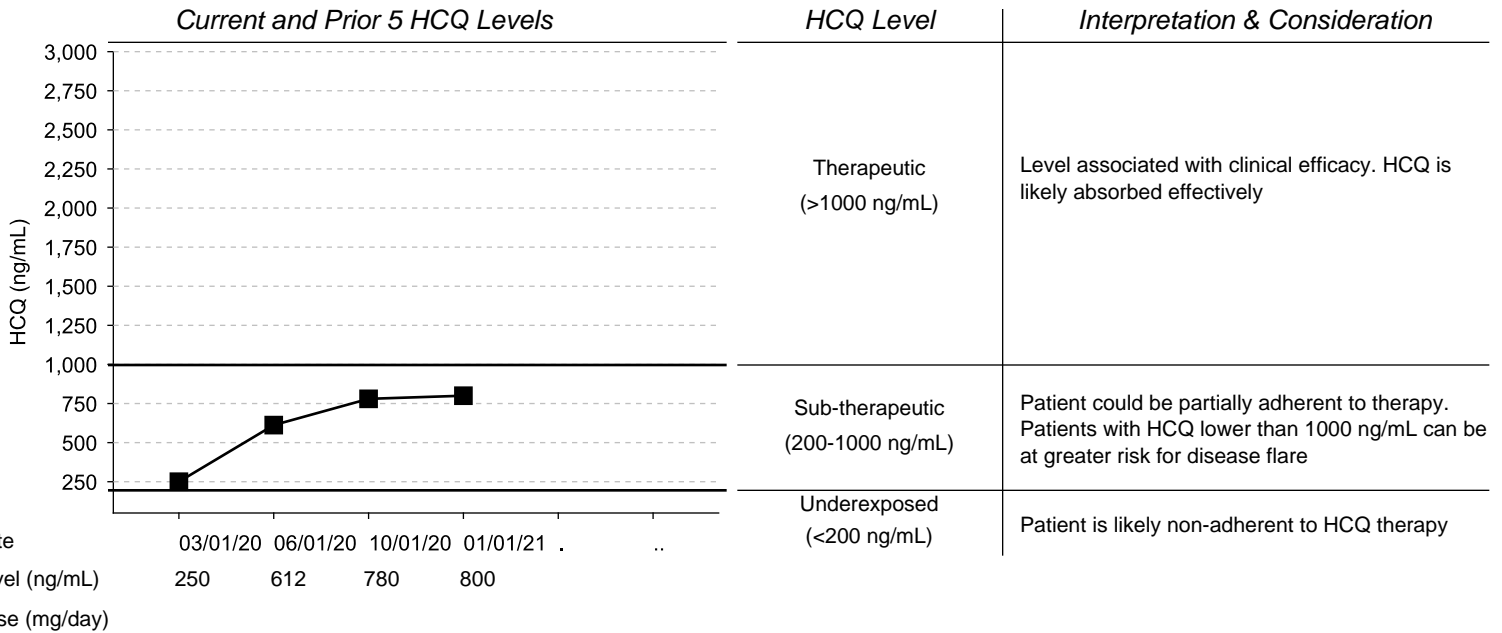
Patient
Patient, Example
 Gender - DOB Female - 01/12/1990
 Identifier Received
 Exagen ID 707382

Avise HCQ Test Report

Current Hydroxychloroquine (HCQ) Level:

800 ng/mL - Sub-therapeutic

HCQ Dose (mg/day)



Test Method Description

HCQ concentration is determined by liquid chromatography coupled with mass spectrometry (LC/MS/MS). This test has not been validated in pediatric populations. The HCQ blood level should be evaluated after 6 months of HCQ therapy - it has not been validated in patients treated for less than 6 months. This test cannot be used to assess the risk of HCQ toxicity.

References

1. Costedoat-Chalumeau N, et al. Low blood concentration of hydroxychloroquine is a marker for and predictor of disease exacerbations in patients with systemic lupus erythematosus. *Arthritis Rheum.* 2006 Oct;54(10):3284-90.
2. Costedoat-Chalumeau N, et al. Very low blood hydroxychloroquine concentration as an objective marker of poor adherence to treatment of systemic lupus erythematosus. *Ann Rheum Dis.* 2007 Jun;66(6):821-4.
3. Costedoat-Chalumeau N, et al. (2013a) Hydroxychloroquine in Systemic Lupus Erythematosus: Results of a French Multicentre Controlled Trial (PLUS Study). *Ann Rheum Dis* 72:1786-1792.
4. Costedoat-Chalumeau N, et al. (2013b) Adherence to Treatment in Systemic Lupus Erythematosus Patients. *Best Pract Res Clin Rheumatol* 27:329-340.
5. Frances C, et al. Low blood concentration of hydroxychloroquine in patients with refractory cutaneous lupus erythematosus: a French multicenter prospective study. *Arch Dermatol.* 2012 Apr;148(4):479-84.
6. Exagen Diagnostics, Inc. Data on File.



1261 Liberty Way, Vista CA 92081
 CLIA# 05D1075048
 CAP# 7201051 | NYSDOH PFI# 8369

Laboratory Directors:
 Richard Safrin, MD
 R. Harper Summers, MD

Provider Relations: 888.452.1522
 AVISE and the AVISE and Exagen logos are registered trademarks of Exagen Inc. ©2021 All Rights Reserved