HEMOSTASIS AND THROMBOSIS
INTERPRETIVE SAMPLE REPORTS

LabCorp
Laboratory Corporation of America

SPECIALIZED COAGULATION STUDIES REPORTS TO HELP GUIDE CLINICAL DECISION-MAKING

Diagnosis of disorders of hemostasis and thrombosis is complex and requires integrated evaluation of multiple laboratory tests. Pre-analytical variables such as anticoagulant therapy at the time of draw can further complicate test interpretation. LabCorp and its specialty laboratory, Colorado Coagulation, now offer two profiles that incorporate clinical decision support reports to assist physicians in diagnosis of certain common hemostatic disorders, specifically antiphospholipid syndrome and von Willebrand disease.

Sample Clinical Decision Support Report for Antiphospholipid Syndrome
(includes guideline-based follow-up testing recommendations)

1. Profiles established using current International Society of Thrombosis and Hemostasis (ISTH) and Clinical Laboratory Standards Institute (CLSI) guidelines

2. Clinical assessment is summarized and defined for easy review.

3. Previous laboratory results appear as a flow sheet for historical reference. Visual representation of test results over time allow for comprehensive evaluation of the patient.

PATIENT	DATE OF BIRTH	GENDER	DATE OF SERVICE	PHYSICIAN
Case 3, Sample 2	**11/11/1111**	**F**	**11/11/1111**	**Sample Physician**
				LabCorp Account #: 11111111

Accessions: 11111111111

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DISCLAIMER: *These assessments and interpretations are provided as a convenience in support of the physician-patient relationship and are not intended to replace the physician's clinical judgment. They are derived from the national guidelines in addition to other evidence and expert opinion. The clinician should consider this information within the context of clinical opinion and the individual patient.*
SEE GUIDANCE FOR ANTIPHOSPHOLIPID SYNDROME ASSESSMENT:(1) Pengo V et al. J Thromb Haemost. 2009; 7(10):1737-1740. (2) Miyakis S et al. J Thromb Haemost. 2006;4(2):295-306. (3) Garcia DA et al. Blood. 2007;110(9): 3122-3127.

Note: *Please refer to your LabCorp Report for all results as well as any test-specific and specimen-specific comments.*

Coagulation Studies
Interpretive Assessment and Summary

Antiphospholipid Syndrome Assessment

Assessment

A lupus anticoagulant is detected. aCL and B2GP1 antibodies are normal.

Summary

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Persistence of a lupus anticoagulant has been demonstrated and fulfills the laboratory criteria for antiphospholipid syndrome (J Thromb Haemost. 2006; 7(10):1737-1740) even though aCL and B2GP1 antibody results on both occasions have not met laboratory criteria for antiphospholipid syndrome. The risk for recurrent thrombosis and obstetric complications is increased in patients with persistent aPL (JAMA 2006; 295(9):1050-1057); risk increases with both the titer and number of aPL detected (Thromb Haemost. 2003; 90(1):108-115). The general consensus is to treat patients with thrombosis and persistent aPL with an indefinite duration of anticoagulant therapy (Blood 2007; 110(9):3122-3127). Asymptomatic individuals who are persistently positive for aPL have a low annual incidence of thrombosis (Arthritis Rheum 2007; 56(7):2382-2391). However, individuals with persistent aPL may benefit from thromboprophylaxis in high risk situations such as surgery, the post-partum period and prolonged immobilization.

Definitions

aCL- anticardiolipin (antibodies to cardiolipin); LA- lupus anticoagulant (which is identified with the dRVVT and/or hexagonal phospholipid neutralization assays); aPL- antibodies to protein/phospholipid complexes such as LA, aCL, and B2GP1 antibodies; APS- antiphospholipid syndrome; DTI-direct thrombin inhibitors.

Medical Director:

For questions regarding panel interpretation, please contact Dorothy (Adcock) Funk, M.D., or Karen Moser, M.D. at Esoterix Coagulation at 1-800-444-9111.

Flow Sheets

The 8 most recent lab results are reported.

Antiphospholipid Syndrome Assessment

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Date	aPTT	aPTT 1:1 NP	Prothrombin Time	INR	Thrombin Time	Thrombin Neutralization	dRVVT	dRVVT Confirm	Hexagonal Phase Phospholipid	Anticardiolipin Ab, IgG	Anticardiolipin Ab, IgM	Beta-2 Glycoprotein Ab, IgG	Beta-2 Glycoprotein I Ab, IgM
06/03/13	**42.0**	**37.0**	**13.2**	**1.1**	**18.0**	**n/a**	**58.0**	**1.9**	**15.0**	**<10**	**<10**	**<10**	**<10**
01/04/13	43.0	37.0	13.2	1.1	17.0	n/a	60.0	2.0	13.0	<10	<10	<10	<10
Ref. Interval	23.4-36.4	23.4-36.4	11.9-14.1	0.8-1.2	0.0-20.0		0.0-55.1	0.0-1.4	0.0-8.0	0-14	0-12	0-20	0-32

LabCorp Laboratory Corporation of America

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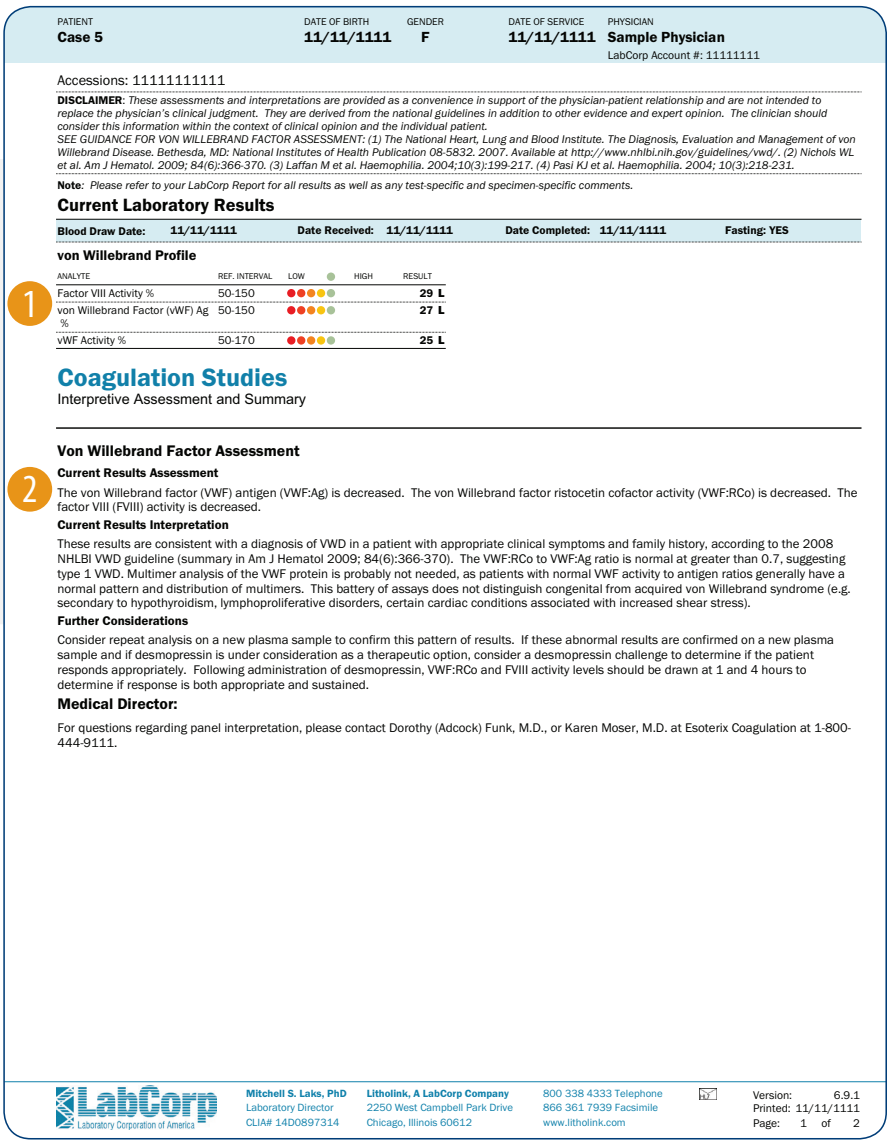
Sample Clinical Support Report for von Willebrand Disease Profile
(includes guideline-based follow-up suggestions)

1. Visual cues highlight test results
   - Green — results within reference range
   - Red — progressive deviation from reference range

   Values outside of reference range may also be printed in bold and annotated as high or low

2. Interpretive assessment included



PATIENT **Case 5** | DATE OF BIRTH **11/11/1111** | GENDER **F** | DATE OF SERVICE **11/11/1111** | PHYSICIAN **Sample Physician**
LabCorp Account #: 11111111

Accessions: 11111111111

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SEE GUIDANCE FOR VON WILLEBRAND FACTOR ASSESSMENT: (1) The National Heart, Lung and Blood Institute. The Diagnosis, Evaluation and Management of von Willebrand Disease. Bethesda, MD: National Institutes of Health Publication 08-5832. 2007. Available at http://www.nhlbi.nih.gov/guidelines/vwd/. (2) Nichols WL et al. Am J Hematol. 2009; 84(6):366-370. (3) Laffan M et al. Haemophilia. 2004;10(3):199-217. (4) Pasi KJ et al. Haemophilia. 2004; 10(3):218-231.

Note: *Please refer to your LabCorp Report for all results as well as any test-specific and specimen-specific comments.*

Current Laboratory Results

Blood Draw Date: 11/11/1111 **Date Received:** 11/11/1111 **Date Completed:** 11/11/1111 **Fasting:** YES

von Willebrand Profile

ANALYTE	REF. INTERVAL	LOW	HIGH	RESULT
Factor VIII Activity %	50-150			**29 L**
von Willebrand Factor (vWF) Ag %	50-150			**27 L**
vWF Activity %	50-170			**25 L**

Coagulation Studies
Interpretive Assessment and Summary

Von Willebrand Factor Assessment

Current Results Assessment

The von Willebrand factor (VWF) antigen (VWF:Ag) is decreased. The von Willebrand factor ristocetin cofactor activity (VWF:RCo) is decreased. The factor VIII (FVIII) activity is decreased.

Current Results Interpretation

These results are consistent with a diagnosis of VWD in a patient with appropriate clinical symptoms and family history, according to the 2008 NHLBI VWD guideline (summary in Am J Hematol 2009; 84(6):366-370). The VWF:RCo to VWF:Ag ratio is normal at greater than 0.7, suggesting type 1 VWD. Multimer analysis of the VWF protein is probably not needed, as patients with normal VWF activity to antigen ratios generally have a normal pattern and distribution of multimers. This battery of assays does not distinguish congenital from acquired von Willebrand syndrome (e.g. secondary to hypothyroidism, lymphoproliferative disorders, certain cardiac conditions associated with increased shear stress).

Further Considerations

Consider repeat analysis on a new plasma sample to confirm this pattern of results. If these abnormal results are confirmed on a new plasma sample and if desmopressin is under consideration as a therapeutic option, consider a desmopressin challenge to determine if the patient responds appropriately. Following administration of desmopressin, VWF:RCo and FVIII activity levels should be drawn at 1 and 4 hours to determine if response is both appropriate and sustained.

Medical Director:

For questions regarding panel interpretation, please contact Dorothy (Adcock) Funk, M.D., or Karen Moser, M.D. at Esoterix Coagulation at 1-800-444-9111.

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Antiphospholipid Syndrome 117079

Specimen 3 tubes - 2 mL each frozen citrated plasma, and 1mL frozen serum. Ship frozen.
Methodology Clot, enzyme-linked immunosorbent assay (ELISA)
Profile Includes Activated partial thromboplastin time (APTT); APTT 1:1 NP; PT/INR; Thrombin Time; Thrombin Neutralization ; dilute Russell's viper venom time (dRVVT); dRVVT confirmation; hexagonal phase neutralization; anticardiolipin Ab, IgG/IgM Beta-2 glycoprotein I Ab, IgG/IgM. Includes interpretive assessment.

von Willebrand Factor Profile 084715

Specimen 3 mL citrated plasma. Ship frozen.
Methodology Clot, Platelet Agglutination, LIA
Profile Includes Factor VIII Activity, von Willebrand Factor (vWF) Activity, von Willebrand Factor (vWF) Antigen. Includes interpretive assessment.

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