

# DRVVT Method Comparison Study on Patients Receiving Anticoagulant Therapy



Maria Notini, MT, ASCP, Thomas L. Ortel, MD, PhD  
Duke University Hospital; Durham, North Carolina

Presented at THSNA 2020 Oct 27-30

## Background

- Accurate diagnosis of patients with a lupus anticoagulant (LA) is critical when assessing patients for possible antiphospholipid syndrome (APS).
- Testing patients while they are taking anticoagulant therapy can result in false positive results for LA.
- The aim of this study was to compare the ability of two manufacturers' dRVVT assays to detect the presence of LA in order to aid in the diagnosis of APS.

## Objectives

### Primary Objective

To evaluate dRVVT assays from two different manufacturers and evaluate their ability to detect the presence of lupus anticoagulant to aid in the diagnosis of antiphospholipid syndrome.

### Secondary Objective

To evaluate the impact of different anticoagulant therapies on dRVVT results for known positive or negative samples.

## Methods

- Fifty patient samples were tested and compared using two different dRVVT screen and confirm assays: DVVtest®/DVVconfirm® from Biomedica Diagnostics (Reagent 1), and LA Check™/LA Sure™ from Precision BioLogic (Reagent 2).
- In some instances when it was determined that the sample was negative by the screening assay, a confirmatory assay was not performed (n=3).
- Any sample that tested positive by Reagent 1 or Reagent 2 was further tested to determine if an oral anticoagulant (OAC) was present and if this was interfering with the assay.

## Method Comparison

Figure 1. Correlation between Reagent 1 (X) and Reagent 2 (Y) screening tests

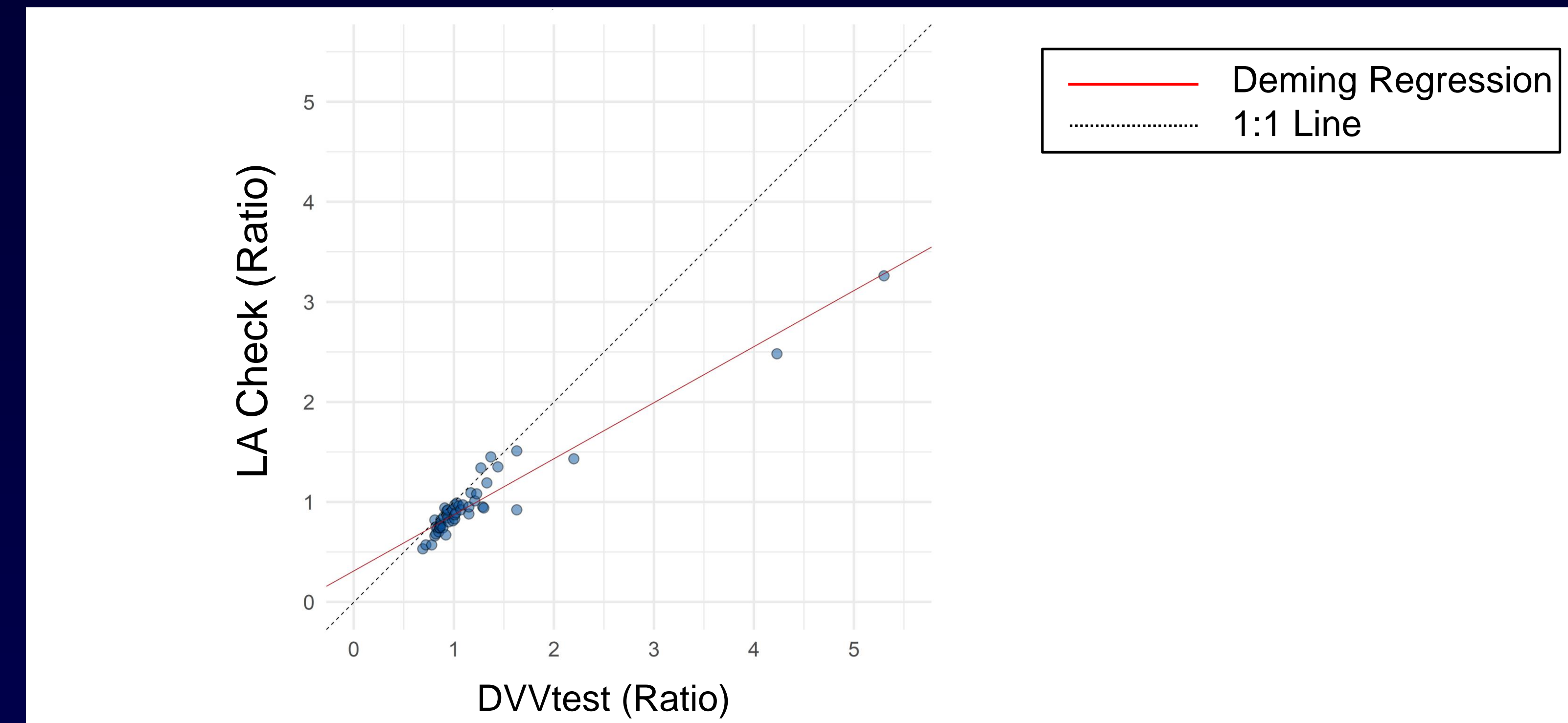


Figure 2. Correlation between Reagent 1 (X) and Reagent 2 (Y) confirmatory tests

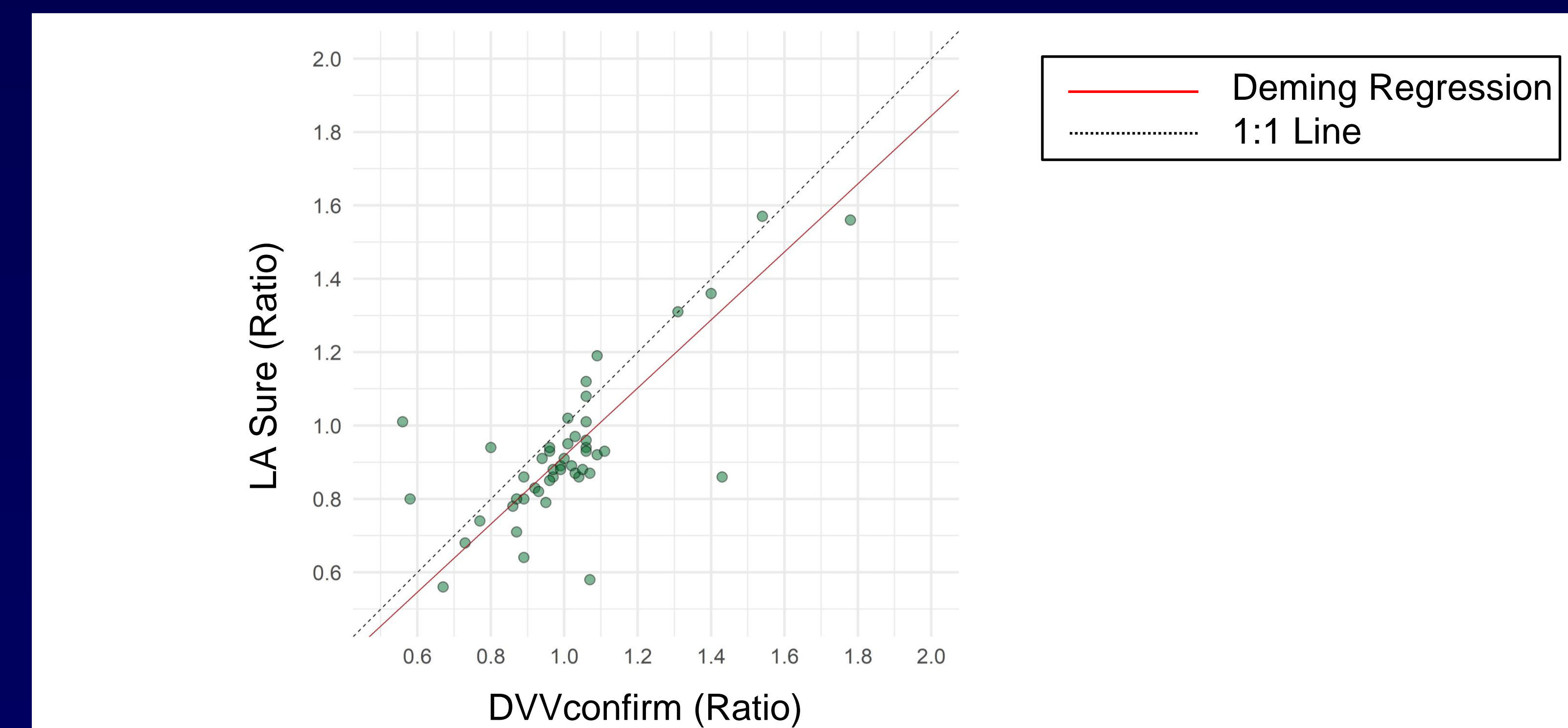


Table 1. Agreement between Reagent 1 and Reagent 2 for dRVVT screen assay

	Reagent 2 Positive	Reagent 2 Negative
Reagent 1 Positive	7	6
Reagent 1 Negative	0	37

## Results

- Testing showed that both assays were able to accurately detect LA, and correlation between the two assays was excellent ( $r=0.9596$  for screening test) (Figure 1).
- A small number of discrepant samples from patients on OAC in the study were falsely reported as positive for LA. These samples all tested positive for LA with Reagent 1, whereas the Reagent 2 correctly identified these samples as negative in 6 out of 8 instances (Table 1).
- In one instance a sample that tested positive by both screening assays tested positive by Reagent 1 and negative by Reagent 2 by confirmatory assay. This patient was confirmed to be LA negative.

Table 2. Oral Anticoagulants detected in test samples

Drug	Level Detected
Apixaban	N/A*
Warfarin	N/A*
Apixaban	224 ng/mL
Rivaroxaban	230 ng/mL
Apixaban	69 ng/mL
Rivaroxaban	180 ng/mL
Warfarin	INR=1.4
Warfarin	INR=2.8

\*Data not available

## Conclusions

- Both reagents performed similarly and were able to accurately detect the presence of LA when OAC were not present.
- Only one sample produced discrepant results with Reagent 2 correctly identifying the sample as negative for LA by confirmatory test.
- Some interference was observed when testing samples with OAC at various levels (Table 2), causing false positive results.
- This interference affected Reagent 1 at a higher rate than Reagent 2.