

ANALYTICAL AND CLINICAL VALIDATION OF A POINT-OF-CARE ASSAY FOR LIPASE ACTIVITY DETERMINATION IN CANINE SERUM

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Background

Serum lipase is a glycoprotein, which is used for the diagnosis of pancreatitis. However, pancreatitis would not be the only cause that can lead to elevations of serum lipase and a definitive diagnosis should be made taking into account the overall clinical and laboratory data of the patient¹. In spite of this, the determination of lipase can be highly sensitive, since normal values help to rule out pancreatitis. There are different methods for the determination of circulating lipase in dogs that have different sensitivity and specificity. Thus for correct result interpretation the type of the assay used should be taken into account.²

Objective

The objective of this study was to validate the FUJI DRI-CHEM v-LIP-P (v-LIP; Fig.1), a dry chemistry method, for lipase measurements in canine serum and to compare with two other laboratory assays using 1,2-o-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin) ester (DGGR) and 1,2-diglyceride (DiG) as substrates.

Methods

- **Analytical validation:** performed by evaluation of assay precision, accuracy (by serial dilutions and recovery tests) and detection limit (DL).
- **Clinical validation:** serum samples, collected in San Marco Veterinary Clinic (Veggiano, Padova, Italy), of 73 dogs from with compatible signs of pancreatitis were used. These were classified as:
 - **Non-pancreas-related diseases** (Group 1; $n = 45$) dogs with different pathology and diseases that showed clinical signs compatible with pancreatitis.
 - **Pancreatitis** (Group 2; $n = 28$) confirmed by biochemistry analysis and ultrasonography.
- Samples from both groups were measured for lipase activity with v-LIP (Fujifilm®; Fig.1), DGGR and DiG methods. A receiver operation characteristic (ROC) analysis was performed to evaluate their clinical use in pancreatitis diagnosis.

Results and Discussion

- **Analytical validation:**
 - The coefficient of variation (CV) obtained for the intra-assay was <3% while the inter-assay was <2%. Linearity under dilution test resulted in a linear regression equation with correlation coefficients of 0.99. The method showed mean recovery rate of 94.4%. The DL was 27.37 IU/L.
- **Clinical validation:**
 - All three assays showed higher lipase activity in Group 2 dogs in comparison with Group 1 ($P < 0.001$). (Fig.2). The results showed that the v-LIP method allowed to differentiate between animals suffering from pancreatitis and animals with similar clinical signs but without pancreatitis. The area under the ROC curve was higher for the v-LIP (90.4%) than for the other two methods (82.1% and 84.1% for the DiG and DGGR, respectively) (Fig.3).

Conclusion

v-LIP allows the determination of lipase activity in canine serum with high precision, accuracy and sensitivity and showed higher ROC curves for detection of pancreatitis compared to DGGR and DiG based assays.

Bibliography

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2. Graca, R., Messick, J., McCullough, S., Barger, A., Hofmann, W. Validation and diagnostic efficacy of a lipase assay using the substrate 1,2-o-dilauryl-rac-glycero glutaric acid-(6' methyl resorufin)-ester for the diagnosis of acute pancreatitis in dogs. Vet. Clin. Pathol. 34 (1), 39-43 (2005).



Fig.1. FUJI DRI-CHEM NX500

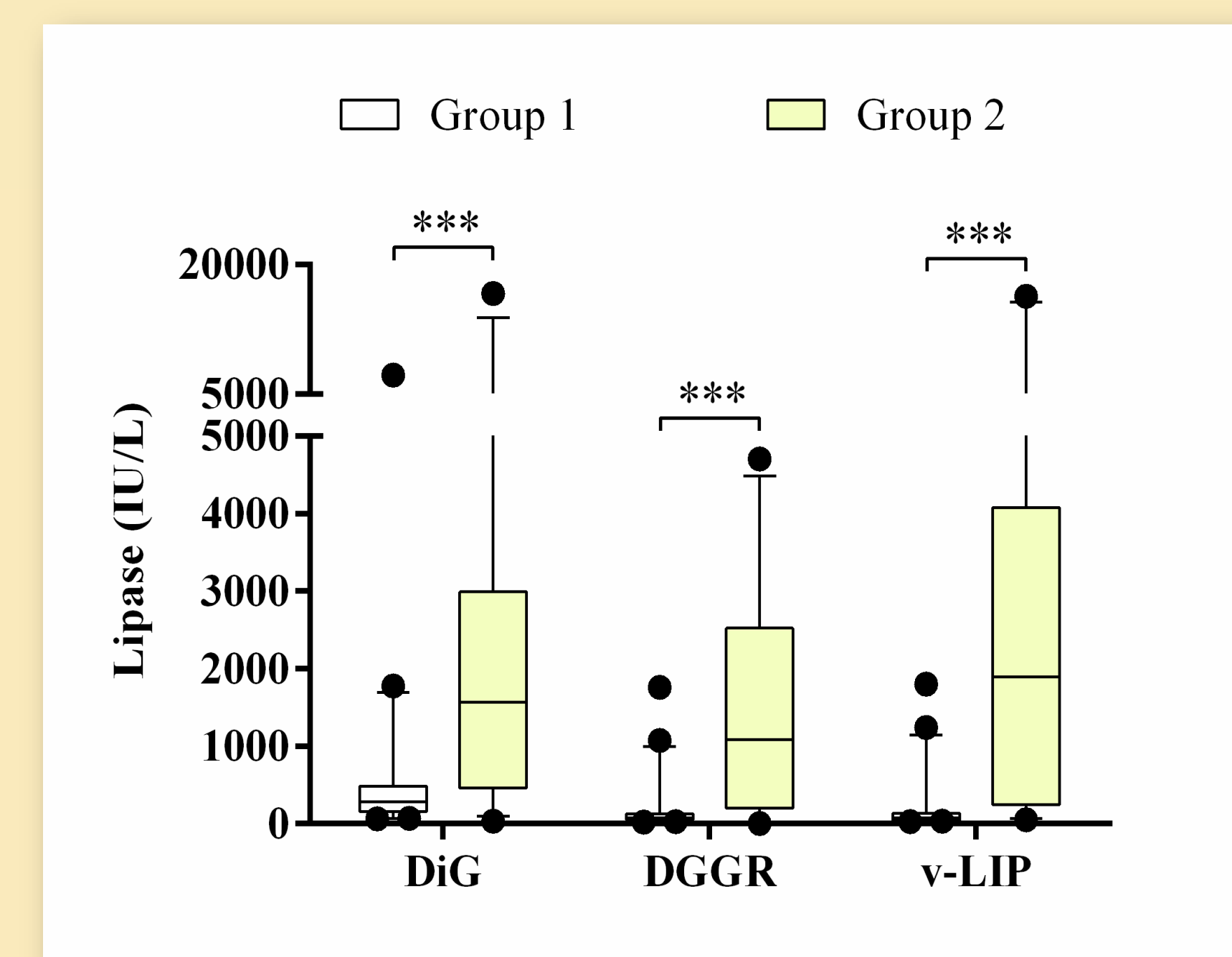


Fig.2. Serum Lipase results obtained with the three methods in animal with non-pancreas-related disease (group 1) and animal with pancreatitis (group 2). The plot shows median (line within box), 25th and 75th percentiles (box), minimum (5th percentiles) and maximum (95th percentiles) (whiskers). Statistically significant differences between groups were represented by asterisks (***) $p < 0.001$.

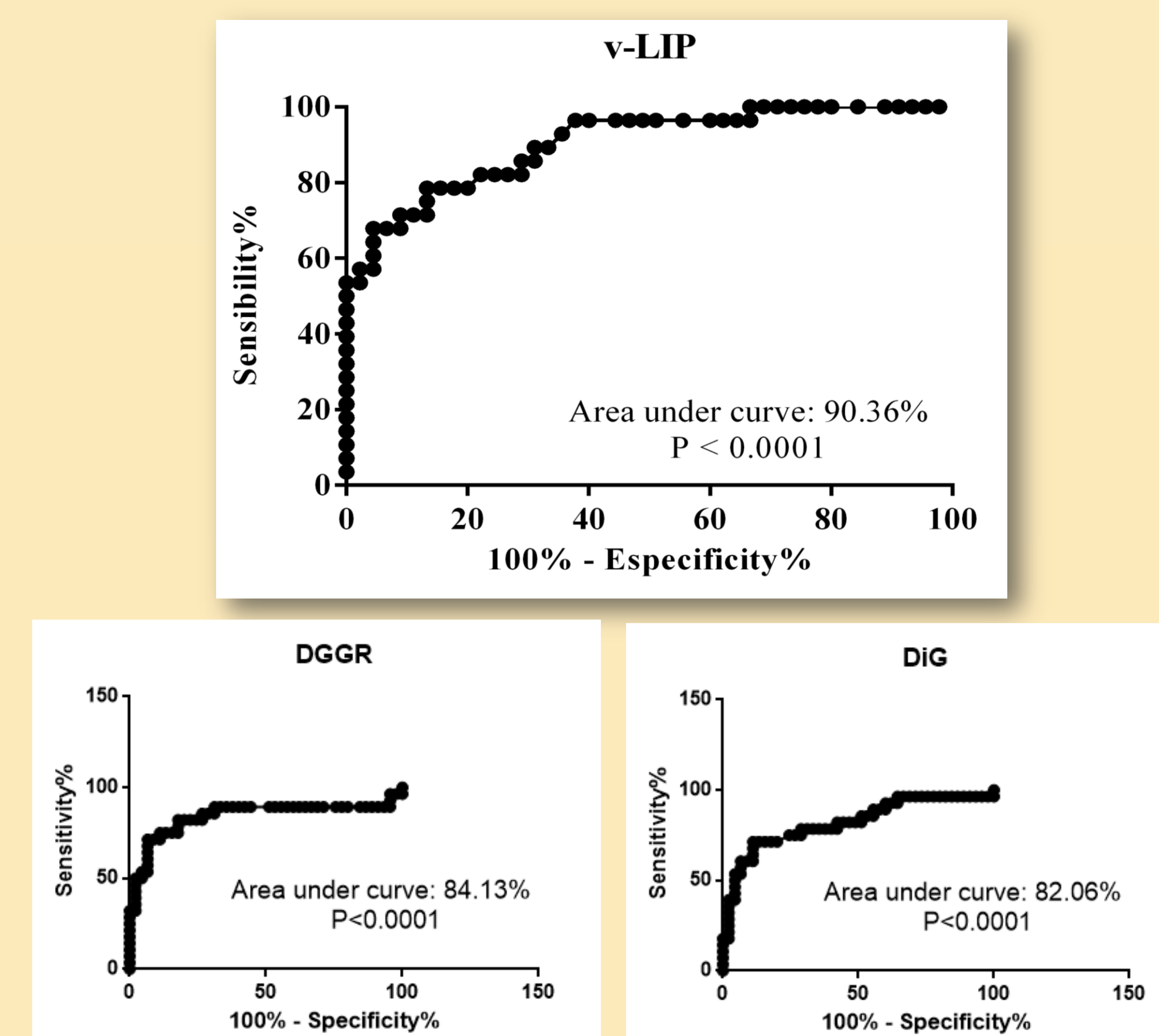


Fig.3. The receiver operation characteristic (ROC) analysis obtained for (a) FUJI DRI-CHEM (v-LIP), (b) DiG and (c) DGGR methods.