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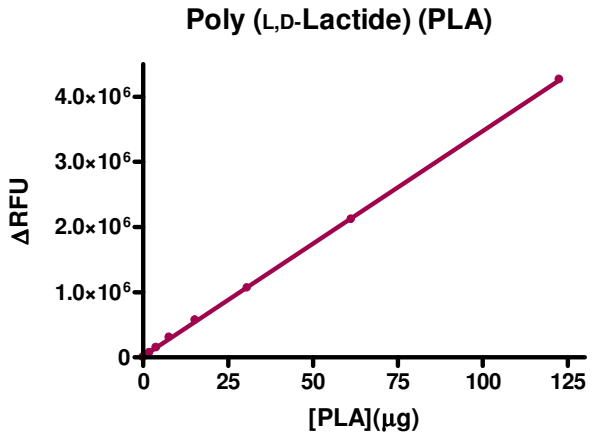
Title: Quantitation of Polylactate-containing Polymers

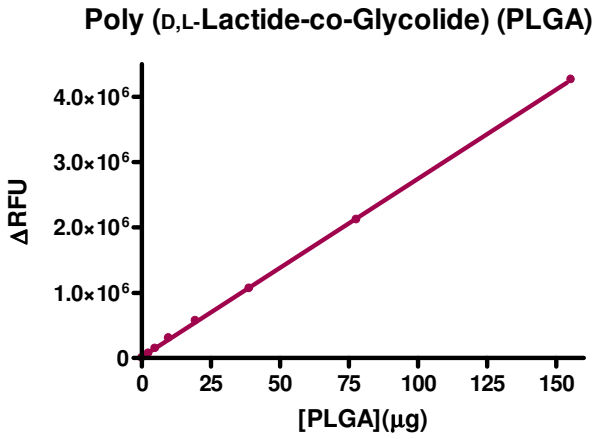
Summary

BioAssay Systems has developed a kinetic fluorometric assay to quantify D-lactate containing polymers, such as PLA and PLGA in tissue samples. The assay principle is based on the hydrolysis of D-lactate containing polymers into lactate monomers followed by D-lactate determination using a highly sensitive and specific fluorescence method. Only L-lactate is naturally prevalent in animal tissue (D-lactate is typically present at only nM levels in mammals which is below the detection limit of the current assay); therefore, any D-lactate measured in a sample is solely derived from the polymer present in the sample.

Key Features of the Assay

- Useful to assess remaining polymer coatings on implanted medical devices.
- Two step process: 1) Hydrolysis of polymer present to monomers and 2) Measurement of D-lactate.
- Accuracy and sensitivity of the assay are not affected by polymer MW, which will decrease over time during implantation.
- The method uses D-lactate as a biomarker and since D-lactate is not found endogenously above nM concentrations, the assay is highly specific for PLA.
- There is no requirement to remove the tissue from sample, the PLA on both the device and in the tissue are measured together.
- Depending on the nature of the sample and polymer composition, sensitivities as low as 1 microgram are possible.





Bioassay Systems has successfully performed this service to measure the degradation of polymer coatings on implanted devices for 3 different medical device companies. Results from these projects

were critical for two CE Mark Approvals and the FDA approval of two medical device Investigational Device Exemption (IDE) applications.

This service includes the final preparation of samples for the assay, the hydrolysis of polymer in samples down to monomers and enzymatic measurement of the resultant D-lactate monomers. The polymer weight in the sample is computed from the measured D-lactate concentration in the hydrolysis reaction. The client will be issued a report summarizing the results of the analysis along with an Excel spreadsheet containing all of the collected data, data analysis and results.

BioAssay Systems scientists have strong expertise and >50 years of experience in assay development. Over the past years, we have developed over 170 assay kits for research and drug discovery (please visit our website www.bioassaysys.com). These assay products are rapid, sensitive, high-throughput, convenient and simple to use. In addition to selling its assay products, BioAssay Systems provides assay development and analytical services and has successfully offered analytical services to food, biotech and pharmaceutical companies. These services included a wide variety of projects including developing assays to trouble shoot processes, performing screening assays and performing analytical assays for FDA submittals.