17 July 2026

Change Control Notification Document # 0011

Please distribute this information to the appropriate departments and personnel within your organization.

Description of Change

Athens Bioscience is notifying customers of an update to the Superoxide Dismutase (SOD) activity assay used to generate Certificates of Analysis (COAs) for Superoxide Dismutase Cat # 16-05-191504.

The manufacturer of the Life Technologies Superoxide Dismutase (SOD) Colorimetric Activity Kit (Catalog No. EIASODC) has updated the assay methodology. The revised assay no longer utilizes the calculation modifier that was included with the previous version of the assay kit.

As a result, Athens Bioscience has updated its SOD activity calculations, activity specification, and Certificate of Analysis language to align with the manufacturer's current methodology.

Reason for Change

This change has been implemented to align our reported SOD activity values and Certificate of Analysis language with the current methodology specified by the assay kit manufacturer.

The update reflects a change in the analytical calculation and reporting methodology only and does not represent a change to the product, manufacturing process, formulation, purity, or product quality.

Impacted Documents

- Certificates of Analysis (COAs)
- Product Specifications (minimum activity specification)
- Internal analytical test method documentation
- Related change control documentation

Timing of Change

Effective Immediately

All future Certificates of Analysis will reflect the updated assay methodology, revised activity specification, and updated activity statement.

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ATHENS BIOSCIENCE, INC.™

Additional Information

The minimum activity specification has been updated as follows:

Previous Specification

>50,000 U/mg

Current Specification

>2,500 U/mg

The activity statement appearing on the Certificate of Analysis has also been updated to reflect the manufacturer's current assay documentation.

Previous Activity Statement

One unit is defined as the amount of enzyme which will inhibit by 50% the formation of a colorimetric indicator by O_2^- in a xanthine/xanthine oxidase coupled system.

Current Activity Statement

One unit of SOD is defined as the amount of enzyme causing half the maximum inhibition of the oxidation of 7.5 mM NADH in the presence of EDTA, manganese ions, and mercaptoethanol at 23°C and pH 7.4 over 15 minutes.

These updates are the result of the manufacturer's revised assay methodology and documentation. There has been no change to the identity, purity, manufacturing process, formulation, or expected performance of the SOD product.

For any questions regarding this notification, please contact our Technical Support team at **technical@athensbioscience.com**.

Best Regards,

Kimberly Kesler
Quality Representative

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Document example description:

ATHENS BIOSCIENCE, INC.™

CERTIFICATE OF ANALYSIS

Product Name:	**Superoxide Dismutase**
Catalog #:	16-05-191504 **Lot Number: SOD20XX-XX**
Source:	Human Erythrocytes
Unit Size:	1,000 Units, 10,000 Units, 30,000 Units
Form:	Lyophilized
Buffer:	0.1M potassium phosphate, pH 7.5
Concentration:	mg/mL prior to lyophilization
Minimum Activity:	2,500 U/mg **Specific Activity:** U/mg
Activity:	One unit of SOD is defined as the amount of enzyme causing half the maximum inhibition of the oxidation of 7.5 mM NADH in the presence of EDTA, manganese ions, and mercaptoethanol at 23°C and pH 7.4 over 15 minutes.
Storage/Handling:	≤ -20 °C
Purity:	≥ 95% by SDS-PAGE
Manufacture Date:	DD/MMM/YYYY **Expiration Date:** DD/MMM/YYYY
Important:	Reconstitution: After centrifugation, we suggest the addition of de-ionized water to the original volume, followed by gentle mixing to ensure adequate homogenization. If further dilution is required, please use the lyophilization buffer.
Applications	Specific applications have not been determined for this product.
Testing:	Donor material is obtained from suppliers that perform a comprehensive infectious disease screening panel. Donor red blood cell units were tested individually by the supplier and found non-reactive for HIV-1/2, Hepatitis B (HBsAg and HBV DNA), Hepatitis C (HCV Ab and HCV RNA), syphilis, West Nile virus (WNV), and Chagas (T. cruzi). Blood group and Rh type were also confirmed. Testing documentation is maintained and available upon request.
Notes:	To ensure complete recovery of product, please centrifuge prior to opening.

FOR RESEARCH OR FURTHER MANUFACTURING USE ONLY