

VL01-0000000830 2025年5月吉日

お客様各位

株式会社ベリタス バイオサイエンス本部 営業グループ マネージャー 平元 高広 担当 佐藤 洋輔 (TEL:03-5776-0078)

<u>Streck 社 RNA Complete BCT 販売終了のお知らせ</u>

拝啓 向夏の折、貴社ますますご清栄のこととお慶び申し上げます。

平素は Streck 社の RNA Complete BCT 商品について格別のご愛顧を賜り、厚く御礼申し上げます。 この度、RNA Complete BCT の販売を終了いたしますので、下記の通りご案内申し上げます。恐れ入りま すが、後継商品への切り替えをご検討くださいますようお願いいたします。

お客様にはご不便をおかけいたしますが、今後もより一層のサービス向上に努めてまいりますので、変わらぬご高配を賜りますようお願い申し上げます。

敬具

記

■ 対象商品と後継商品

販売終了商品		後継商品	
STK-230460	RNA Complete BCT	STK-230644	Nucleic Acid BCT
	10.0mL x 6 tubes		10.0mL x 6 tubes
STK-230461	RNA Complete BCT	STK-230645	Nucleic Acid BCT
	10.0mL x 100 tubes		10.0mL x 100 tubes
STK-230462	RNA Complete BCT	STK-230646	Nucleic Acid BCT
	10.0mL x 1000 tubes		10.0mL x 1000 tubes

■ 販売終了日

2025年6月6日

■ 対応方法

後継商品は、Nucleic Acid BCT 商品となります。

A GLOBAL BIOTECHNOLOGY MARKETING COMPANY

株式会社ベリタス Veritas Corporation

www.veritastk.co.jp

〒105-0013 東京都港区浜松町1-18-16住友浜松町ビル6階 Tel:03-5776-0078(代) Fax:03-5776-0076



現在、RNA Complete BCT をご利用のお客さまは、Nucleic Acid BCT への切り替えをご検討ください。なお Nucleic Acid BCT に使用されているガラス材、ストッパー材、試薬は RNA Complete BCT と同一です。また両商品の性能は同等です。詳細は添付文書をご確認ください。



添付文書(RNA Complete BCTとNucleic Acid BCTの同等性に関するメーカー文書) Nucleic Acid BCT and RNA Complete BCT Letter of Equivalence Nucleic Acid BCT vs RNA Complete BCT report

■ お問い合わせ先

株式会社ベリタス バイオサイエンス本部 営業グループ 電話 : 03-5776-0078(代表)

以上

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Dear Valued Customer,

This is to notify you that Nucleic Acid BCT[™] (10 mL) is comprised of the same glass material, stopper material and reagent as RNA Complete BCT[®]. The volume of reagent in Nucleic Acid BCT (10 mL) is equivalent to RNA Complete BCT. The performance characteristics of each tube are equivalent.

Nucleic Acid BCT (10 mL) is For Research Use Only. Not for use in diagnostic procedures. Nucleic Acid BCT (10 mL) should only be used for research or the development of new assays.

Kind Regards,

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Bill Rock Product Manager



Nucleic Acid BCT[™] (10 mL) and RNA Complete BCT[®] Substantial Equivalence Report

A 10 mL configuration of Nucleic Acid BCT has been developed to provide researchers with approximately twice the amount of plasma as the 5 mL configuration.

This report demonstrates that Nucleic Acid BCT (10 mL) has equivalent performance to RNA Complete BCT as it relates to limiting hemolysis, minimizing changes in plasma volume and maintaining plasma cell-free RNA (cfRNA) and extracellular vesicle (EV) concentration during whole blood sample handling and storage.

Nucleic Acid BCT (10 mL) and RNA Complete BCT are For Research Use Only. Not for use in diagnostic procedures and should only be used for research or in the development of new assays.

The following study and associated data analysis were performed by Streck R&D personnel:

Study:

Venous whole blood from 6 self-declared healthy donors was drawn into Nucleic Acid BCT (10 mL) or RNA Complete BCT and plasma was isolated immediately after draw (Draw time) or after 7 days of ambient temperature storage (Day 7). Plasma samples were screened for hemolysis using the NanoDrap OneC spectrophotometer with the included Hemolysis program. Total recovered plasma weight was measured using a zeroed scale and calculated using the published plasma density of 1.025 g/mL. Nucleic acids were purified from 3 mL of plasma using the QlAamp Circulating Nucleic Acid Kit (QIAGEN[®]), and concentration was measured with the Qubit miRNA Assay (cfRNA). EVs were assayed using the NanoSight NS300. Plasma was diluted into PBS to a concentration within the specified working range of the instrument. Final concentration was then calculated based on dilution used.

Results:

When hemolysis and plasma volume were monitored at draw and after seven days of ambient temperature whole blood storage, we observed that Nucleic Acid BCT (10 mL) and RNA Complete BCT performed almost identically (Figure 1). When cfRNA were analyzed (Figure 2), we observed that both tubes 1) maintained cfRNA concentrations to draw-time levels after seven days of ambient temperature storage and 2) displayed comparable stabilizing performance. A similar trend was observed for EV concentrations, where Nucleic Acid BCT (10 mL) and RNA Complete BCT performed equivalently (Figure 3).





Figure 1. Nucleic Acid BCT (10 mL) and RNA Complete BCT similarly prevent hemolysis and loss of plasma volume during ambient temperature storage. Qualitative (**A**) and quantitative (**B**) analysis of plasma volume loss and hemolysis following seven days of ambient storage in Nucleic Acid BCT (NAC) or RNA Complete BCT (BCT). n=6; ns, not significant by paired T-test. Representative image from a single donor is shown. No significant visual differences were observed between NAC and RNAC BCTs for any of the six donors.



Plasma cfRNA Concentration



Figure 2. Plasma cell-free RNA is maintained to near draw-time levels in blood collected into Nucleic Acid BCT (10 mL) and RNA Complete BCT. Concentration of cell-free RNA in plasma isolated from Nucleic Acid BCT (NAC) or RNA Complete BCT (RNAC) at draw and after seven days of ambient temperature storage. n=6; ns, not significant by paired T-test.

Figure 3. Plasma EV concentrations are maintained to near draw-time levels in blood collected into Nucleic Acid BCT (10 mL) and RNA Complete BCT. Concentration of EVs in plasma isolated from Nucleic Acid BCT (NAC) or RNA Complete BCT (RNAC) at draw and after seven days of ambient temperature storage. n=6; ns, not significant by paired T-test.



Plasma EV Concentration

Conclusion:

Overall, the results of this analysis suggest that Nucleic Acid BCT (10 mL) and RNA Complete BCT have analytically equivalent stabilization performance as it relates to limitation of hemolysis and loss of plasma volume and preservation of draw-time cfRNA and EV concentration.