



NATIONAL BLOOD AUTHORITY
A U S T R A L I A

**Standing Offer for the Supply of Red Cell Diagnostic Products (RCDP)
to Public Laboratories**

Operating Procedures

Version 7

VERSION CONTROL

Updates to these Operating Procedures will be available on the National Blood Authority (NBA) website, www.blood.gov.au Version	Issue Date	Amendments
Version 1.0	1/11/07	-
Version 2.0	1/11/09	-
Version 3.0	8/03/10	-
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FAST FACTS

- A Standing Offer arrangement has been established by the National Blood Authority (NBA) for the supply of Red Cell Diagnostic Products (RCDP) for in vitro use has been set up for use by public laboratories Australia wide.
- This Standing Offer is effective from 1 July 2016 to 30 June 2019 and will operate on arrangements similar to the preceding standing offers with the exception of some product additions and deletions and price changes. Laboratories should refer to these Operating Procedures and the RCDP list to ensure access to the products currently available through this Standing Offer. These documents are available on the National Blood Authority's (NBA's) website at www.blood.gov.au. Changes to the product list or other arrangement updates will be posted on the NBA website as they occur.
- Under the Standing Offer, Bio-Rad Laboratories Pty Ltd, Grifols Australia Pty Ltd, Ortho-Clinical Diagnostics and Immulab Pty Ltd are offering RCDP at the prices listed on the NBA's website at <https://www.blood.gov.au/system/files/Red-cell-diagnostic-product-list-July-2018-final.xlsx%20%282%29.pdf>
- Australian Governments have agreed to subsidise purchases of these RCDP up to a defined limit (Funding Cap), in each of the financial years the Standing Offer is effective.
- After the Funding Cap (the total contract value limit as administered by the NBA under this Standing Offer by Group) has been expended for each of the financial years, public laboratories (Approved Recipients) will pay suppliers directly, for all further purchases made under the Standing Offer.
- Suppliers contact details are available on the NBA's website at <https://www.blood.gov.au/system/files/Supplier-Contact-Details-for-Placing-Orders-for-Red-Cell-Diagnostic-Reagents%281%29.pdf>

GLOSSARY

Approved Recipient – means a Public Laboratory which may place orders under the Standing Offer as notified to the Supplier by the NBA;

Diagnostic Reagent(s) – means the reagents for in vitro diagnostic use available under the Standing Offer. The Red Cell Diagnostics Products are listed on the NBA's website.

Funding Cap – means the amounts notified by the NBA as being the Funding Cap applicable to Approved Recipients (individually or by grouping) in a particular financial year. The Funding Cap amount for each jurisdiction has been determined and agreed to by the Jurisdictional Blood Committee (JBC).

Jurisdictional Blood Committee (JBC) – details about the role of the JBC can viewed at <https://www.blood.gov.au/jbc>

Jurisdictional Representative – means a member of the JBC representing their respective State or Territory or the Commonwealth.

NBA – means the National Blood Authority.

Public Laboratory – means a pathology laboratory funded by State/Territory Government; Therapeutic Goods Administration (TGA) laboratories; educational institutions funded by the Department of Education and Training; Department of Defence laboratories, and laboratories in Commonwealth External Territories funded by the Department of Infrastructure and Regional Development.

Standing Offer – refers to the Deed of Standing Offer for the Supply of RCDP.

Supplier(s) – means a provider of RCDPs as listed on the NBA's website. These organisations are bound by the terms and conditions of the Standing Offer to supply RCDP to Approved Recipients.

INTRODUCTION

1. On 18 January 2016 the NBA released an open Request for Tender (RFT 01/2015) seeking tenderers for the supply of RCDP, the contracts for which expire on 30 June 2019. The tender closed on 23 February 2016.
2. As a result of the procurement process the NBA has established a Deed of Standing Offer for the Supply of RCDP (Standing Offer) with four Suppliers.
3. The panel arrangement will be based on an initial Term of 3 years, commencing 1 July 2016, with an additional one or two periods of one year, in the event that the NBA exercises its option to extend the Term.
4. The Standing Offer provides Australia's Public Laboratories (Approved Recipients) access to a range of RCDP. The Standing Offer provides a competitive supply of RCDP across Australia at competitive prices and agreed service levels.
5. During the period of the Standing Offer, Australian Governments will subsidise to a defined dollar limit, or Funding Cap, the purchase of RCDP from the Standing Offer. Once the Funding Cap is reached, for each financial year, Approved Recipients will fund future purchases themselves.
6. Updates to these Operating Procedures will be posted on the NBA website
7. Refer to the National Blood Authority's website (<https://www.blood.gov.au/red-cell-diagnostic-reagents-product-procurement>) for the following information:
 - RCDP list
 - Current prices and product codes
 - Supplier delivery charges
 - A list of Suppliers on the panel arrangement, including contact details

WHO CAN ACCESS RCDP THROUGH THE STANDING OFFER ARRANGEMENT?

Approved Recipients

8. The Standing Offer is for use by Approved Recipients, specifically:
 - Pathology laboratories funded by State and Territory Governments;
 - Therapeutic Goods Administration (TGA) laboratories;
 - Educational institutions funded by the Department of Education, Science and Training;
 - Department of Defence laboratories; and
 - Laboratories in Commonwealth External Territories funded by the Department of Infrastructure and Regional Development.

THE TERMS AND CONDITIONS OF THE STANDING OFFER

9. There are separate Standing Offers between the NBA and each of the Suppliers. The Standing Offer sets a framework and terms and conditions for the provision of RCDP. It stipulates the Suppliers' roles and responsibilities in relation to receiving orders, filling orders, delivery, record-keeping, invoicing and reporting.
10. The following contractual arrangements will apply, in regard to supply under the Standing Offer up to the time any Approved Recipient's share of the Funding Cap is reached (Pre-Cap) and after the Funding Cap is reached (Post-Cap):

Under Pre-Cap arrangements:

Each time an order is placed under Pre-Cap arrangements the supply of RCDP occurs under the NBA Deed as normal (clause 4). Orders placed create an obligation on the Approved Recipient to:

- Confirm and document correct product delivery
- Pay applicable delivery charges as correctly rendered on suppliers' invoices

Under Post-Cap arrangements:

- Each time an order is placed under Post-Cap arrangements, a contract is created between Suppliers and the Approved Recipient directly. This applies particularly to payment by Approved Recipients of correctly rendered invoices from Suppliers for RCDP ordered, as well as delivery charges.

GENERAL PROCESSES - HOW WILL THE STANDING OFFER OPERATE?

11. The Standing Offer will operate as follows:

Approved Recipients may place orders for RCDP directly with the Suppliers included under the Standing Offer arrangement.

Suppliers will:

- Receive and process orders from the Approved Recipients in accordance with the terms and conditions of the Standing Offer and any other conditions agreed to by the Approved Recipient;
- Supply the Diagnostic Products ordered to the requesting Approved Recipient and provide associated services in accordance with the terms and conditions of the Standing Offer (including defined service levels) and in compliance with the Cold Chain requirements described by the Therapeutic Goods Administration;
- Maintain all appropriate records associated with every delivery of RCDP to any Approved Recipient across Australia as required by an order, and retain proof of delivery and receipt;
- Provide reports to the NBA in accordance with the requirements of the Standing Offer;
- Maintain facilities for receiving and considering customer feedback;
- Invoice the NBA for the cost of RCDP supplied under the Standing Offer to Approved Recipients, until the Funding Cap is reached;
- Once the Supplier has been advised that the Funding Cap is reached, separately invoice the Approved Recipients directly for the cost of the RCDP;
- For every order placed by an Approved Recipient (regardless of whether the order is Pre-Cap or Post-Cap), invoice the Approved Recipient for delivery charges.

12. The Standing Offer does not guarantee the purchase of any product(s) or any volume of products(s) of RCDP from any Supplier.

WHAT RCDP ARE AVAILABLE TO APPROVED RECIPIENTS UNDER THE STANDING OFFER?

13. The RCDP available under the Standing Offer are listed on the NBA website: <https://www.blood.gov.au/system/files/Red-cell-diagnostic-product-list-July-2018-final.xlsx%20%282%29.pdf>, together with information on prices, product codes, presentation size and delivery charges. Suppliers' delivery fees directly to the Approved Recipients on a monthly basis.
14. Over the life of the Standing Offer, Suppliers may choose to reduce their prices. Over the initial Term of the panel arrangement, suppliers who are already on the panel may apply to the NBA to add newly registered RCDP products into the panel arrangement.
15. These products will be evaluated against the requirements of the Request for Tender released by the NBA on 18 January 2016. The NBA expects that applications for new RCDP products will open at the start of each of the calendar years 2016, 2017 and 2018 (subject to the panel arrangement being extended beyond the initial Term of the Deed), in order for newly registered RCDP products to be considered for inclusion in the next supply cycle commencing 1 July in each of the three years.
16. Updates to the price list will be posted on the NBA website: <https://www.blood.gov.au/red-cell-diagnostic-reagents-product-procurement>

HOW APPROVED RECIPIENTS ORDER DIAGNOSTIC PRODUCTS

17. Suppliers' contact details are provided on the NBA website: <https://www.blood.gov.au/system/files/Supplier-Contact-Details-for-Placing-Orders-for-Red-Cell-Diagnostic-Reagents%281%29.pdf>
18. Approved Recipients are responsible for placing their own orders with Suppliers as well as receiving and confirming deliveries. Under no circumstances will the NBA place orders, be in receipt of RCDP or liaise with a Supplier on behalf of an Approved Recipient regarding orders.

CAPPED FUNDING ARRANGEMENTS

Allocation of the Funding Cap

19. The role of the NBA is to administer the Funding Cap on behalf of the State and Territories. Under no circumstances can the NBA allow the national Funding Cap to be exceeded. The allocation of the Funding Cap has been determined and agreed to by the JBC.
20. Approved Recipients will not actually receive the Funding Cap funds from the NBA. Rather, the NBA will pay Suppliers' invoices for orders made under the Standing Offer by Approved

Recipients, until the Funding Cap is reached. Over and above the Funding Cap, Approved Recipients must pay for purchases.

21. The NBA will notify suppliers when Approved Recipients have fully utilised their Funding Cap for the financial year, whereby the supplier will invoice the recipient directly for the remainder of that year, unless advised otherwise by the NBA.
22. Only purchases of RCDP listed on the Standing Offer are covered by the Funding Cap. Approved Recipients wishing to access products that are not listed will be required to make separate arrangements independent of the Standing Offer whereby they will be directly invoiced.
23. Suppliers' delivery charges will not be subsidised by the Funding Cap. Approved Recipients will be required to pay for these charges. Suppliers have been instructed to invoice Approved Recipients separately for delivery charges.

Who will Receive Information about the Funding Cap?

24. Each State and Territory has different arrangements for the purchase of RCDP and consumables. The NBA will provide information surrounding the funding caps to JBC members.

SUMMARY OF RESPONSIBILITIES: NBA, SUPPLIER AND APPROVED RECIPIENTS

NBA Responsibilities

25. The NBA will:

- Administer the Standing Offer arrangement as advised by Jurisdictional Representatives
- Work with Suppliers to implement the Standing Offer arrangements;
- Monitor expenditure against the Funding Cap arrangements, as well as monitor Supplier performance to ensure that the terms and conditions of the Standing Offer are being met;
- Inform Suppliers when:
 - the Funding Cap reaches 80%,
 - the Funding Cap has been expended by an Approved Recipient or Funding Cap Group for the current financial year;
- Provide the Jurisdictional representatives with updates on the Standing Offer arrangements, including expenditure under the Funding Cap and trends in purchasing through the monthly Diagnostic Reagents Invoicing Process (DRIP) reports.

Jurisdictional Representative Responsibilities

26. Jurisdictional Representatives will:

- Provide written advice to the NBA on an annual basis or more frequently upon jurisdictional requirement, concerning the management of funding allocations for Approved Recipients and Approved Recipient Groups;
- Monitor expenditure status against Funding Caps through the monthly DRIP report provided by the NBA;
- Advise Approved Recipients or Approved Recipient Groups of their cap allocation as per the jurisdictional requirement.

Supplier Responsibilities

27. Under the Standing Offer, Suppliers are required to:

- Submit invoices and reports to the NBA in the agreed format within ten business days of the end of each calendar month for RCDP ordered and received by Approved Recipients

during that month under the Standing Offer where Pre-Cap arrangements are applicable;

- Invoice Approved Recipients for RCDP purchased where Post-Cap arrangements are applicable;
- Invoice Approved Recipients for all applicable delivery charges in supplying RCDP; and
- Receive and process orders and deliver RCDP in accordance with the Standing Offer.

Approved Recipient Responsibilities

28. All Approved Recipients are required to:

- Order and use RCDP in a responsible manner;
- Work with members of their Approved Recipient Group to monitor expenditure under the Funding Cap;
- Promptly pay Suppliers' invoices under Post-Cap arrangements; and
- Promptly pay all applicable Suppliers' delivery charges invoiced.

AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (ARTG) STATUS

29. RCDP offered for supply under the Standing Offer arrangement currently meet regulatory requirements for supply in Australia, as administered by the Therapeutic Goods Administration (TGA) and included in the Australian Register of Therapeutic Goods (ARTG).
30. Notwithstanding that the products on the Standing Offer currently meet the TGA's regulatory requirements, the NBA does not in any way, by including these products on the Standing Offer, endorse the efficacy, safety and quality of the products.
31. Under the Standing Offer arrangements, Suppliers must inform the NBA of any change in the regulatory status of their RCDP in terms of meeting TGA requirements during the life of the Standing Offer arrangements. The NBA will update the status of these RCDP on the NBA website, including adding, withdrawing or altering of product(s) from the Standing Offer.

CONTACTING THE NATIONAL BLOOD AUTHORITY

32. For any queries, suggestions, or comments on these Operating Procedures please contact supply.management.plasma@blood.gov.au