the bottle (measured with calibrated infra-red thermometer) remains 0 °C or below. The milk bank employee receiving raw product from a donor must record and initial that these product conditions have been met when logging individual bottles into PREM Bank freezer.

Raw donor human milk is stored frozen at −20 °C by the PREM Bank for a maximum of 3 months from the date of expression. This is consistent with international recommendations [10,11]. Once pasteurised, donor human milk may be stored frozen at −20 °C for a maximum of 3 months prior to being dispensed. Storage freezers are equipped with a power loss and high temperature alarm that is connected to the hospitals building management system. A Business Continuity Plan has also been developed to define an appropriate course of action to maintain a safe supply of pasteurised donor human milk in the event of a freezer (or other process equipment) mechanical failure or power loss.

2.4. Pasteurisation of human milk

International best practice requires that donor human milk must be pasteurised (heated to 62.5 °C for 30 min) prior to being fed to recipients [10,11]. The PREM Bank has committed to meeting this standard. All donor milk is pasteurised at 63.5 ± 1.0 °C for 30 min in a custom built flow-through batch pasteuriser (Saurin Pty Ltd). The pasteuriser is temperature calibrated to ±1.0 °C therefore, this temperature range ensures a minimum of 62.5 °C is obtained. An independently calibrated (NATA) temperature probe logs time and temperature of the product during pasteurisation. This data logger file is permanently maintained with the Batch Record. A batch of milk (600–3000 ml of milk from a single donor) is thawed rapidly in an orbital incubator and pooled into a sterile flask under a laminar flow cabinet. A pre-pasteurisation (1 ml) microbiology sample is taken prior to processing. Once pasteurised, PDHM is transferred to the laminar flow cabinet and post-pasteurisation microbiology (1 ml) and composition (8 ml) samples are taken. PDHM is then aliquoted into volumes required for dispensing to the NICU (14, 50 and 100 ml commercially sterile polypropylene containers).

The efficacy of any pasteuriser is dependent on both the pasteurising temperature and hold time and the time taken to heat and subsequently cool product. This will vary between pasteurisers. The custom built flow-through pasteuriser used by the PREM Bank has been subject to experimental validation prior to use. The efficacy of the PREM Bank pasteuriser at removing bacteria from donor milk while preserving the bioactivity of sIgA has been examined [13]. Effective bacterial removal was observed although a significant reduction in protein bioactivity was observed. Although secretory IgA bioactivity was reduced by 24.5% by pasteurisation, these functional components are not present in artificial formula.

As the first human milk bank to be established in Australia for almost 20 years, the PREM Bank is committed to meeting international guidelines for human milk banking. Currently, pasteurisation at 62.5 °C for 30 min is the most common technique employed [7] and thus, is the standard adopted. However, milk banks must be committed to developing novel techniques to process donor milk to ensure bacterial removal and viral inactivation while preserving the bioactive proteins present in human milk.

2.5. Microbiology methods and standards

When donor milk is under the control of the PREM Bank all processing and storage steps are designed to limit the possible proliferation or contamination of the product by microbiological organisms. All pooling and sampling of donor milk is conducted in a laminar flow cabinet using aseptic technique and all containers that come in contact with the product are commercially sterile. Product is stored at −20 °C to limit lipolysis [14] and microbial growth [15]. Prior to processing milk is rapidly thawed in an orbital incubator (37 °C, 150 rpm) until milk is just thawed (unpublished data has shown that the liquid product temperature at the surface of the bottle did not increase above 0 °C under these conditions). It is common practice for human milk banks to thaw product by submerging bottled donor milk in a water bath. Thawing product in an orbital incubator removes the potential hazard of product contamination due to water entering through the screw cap.

Donor human milk is examined bacteriologically both before and after pasteurisation. Critical limits have been defined for the level of contamination acceptable in raw and pasteurised product. These are required as pasteurisation may not be effective if milk is heavily contaminated [16]. In addition, although pasteurisation kills most organisms, the toxins produced by some bacteria may not necessarily destroyed by heat [16]. The PREM Bank's microbiological standards are based on those used by other human milk banks [11]. A 1 ml sample is taken using aseptic technique from pooled donor milk before pasteurisation (Fig. 1). A second 1 ml sample is taken prior to aliquoting the pasteurised product (Fig. 1). A 10 μL (pre-pasteurisation) and 200 μL (post-pasteurisation) sample are cultured on 5% horse blood and CLED (Cystine-lactose-electrolyte deficient) agar and incubated at 35 °C in 5% CO_2 overnight (18–24 h). Any bacterial growth is identified by standard microbiological techniques. Colony growth is also quantified.

Specific microbiology standards are published elsewhere [11], in general, the pre-sample must contain no potential pathogens capable of producing heat-stable enterotoxins, no Enterobacteriaceae nor enterococci, and no confluent growth of organisms indicating a total count exceeding 10^5 colony forming units per ml. Any bacterial growth in the post-pasteurised sample is unacceptable. Any batch not meeting these standards must be immediately removed from the PREM Bank quarantine freezer.

2.6. Record keeping

The PREM Bank has the operational objective of ensuring full traceability from individual donation to recipient and maintaining a record of all storage and processing conditions. Fig. 2 describes an overview of the record keeping system.

The Donor Record (Fig. 2) consists of the Donor's Unique Medical Record Number (UMRN), Consent and Medical History Questionnaire and Pathology results. This record has been established as a hospital medical record and as such will be maintained according to hospital policy. The Specimen Database (Fig. 2) maintains a log of individual donations made by a donor. Each bottle donated to the PREM Bank is given a unique specimen ID (USID) and the milk bank employee receiving the donation must ensure and record that product temperature and labelling is acceptable. The Specimen Database must also