

STANDARD FOR BLOOD BANK

Name of Facility:

Address:

If comply tick (✓) Yes, if not tick (✗) No. Please add comment for any explanation.

PROVISION	ITEM	YES	NO	COMMENT
	INFRASTRUCTURE & EQUIPMENT			
	Location			
R.50(1)	Free from undue noise (<i>no disturbance to patients & staff</i>)			
R.50(2)	Not exposed to excessive smoke, foul odours or dust			
R.51	Construction prevents entrance and harbourage of rodents and insects			
	Signs and labels			
R.60	Proper signage and labelling system			
	Entrance and exit			
R.54(1)	Door size $\geq 1.2\text{m}$ wide (<i>for patient care</i>)			
R.59(1)	Main entrance adjacent to lobby with minimum disturbance			
R.59(2)	Entrance designed for wheelchairs and stretchers			
R.59(3),(5)	Separate service entrance (<i>close to storage room/area, elevators</i>)			
R.59(3)	Separate patients and visitors entrance			
R.282 (I)	Adequate area for hanging laboratory coats near the entrance or exit door			
R.78	Area for stretchers and wheelchairs			
	Available and displayed in a conspicuous area			
R.36	Duty roster			
R.296(12)	Code of safe conduct (for all personnel)			
R.24(1)(a),(2)	Policy statement on staff identification			
R.24(1)(c),(2)	Policy statement on valid consent-requirement & manner			
R.24(1)(d)(ii),(2)	Policy statement for information on grievance procedure			

PROVISION	ITEM	YES	NO	COMMENT
R.229(1)	Emergency call information (with contact number)			
	Waiting area			
R.282(e)	Separated waiting area from work area			
R.54(1)	Door size $\geq 1.2\text{m}$ wide (<i>for patient care</i>)			
R.58	Adequate ceiling height (air condition $\geq 2.4\text{m}$, if not $\geq 3.0\text{m}$)			
	Reception area/nurse station			
R.282(d)	Separated reception area from work area to receive samples and donors			
R.73(5)	1 station : 36 patients/donors			
R.64(3)	Distance $\leq 24.4\text{m}$ from patients'/donors' rooms			
R.73(2)	Area for writing patients'/donors records & charts (<i>at or nearby</i>)			
R.73(1)(a)	With a nurse call system from patients/donors			
R.73(1)(b) & (c), R.120	Communication system available within & with other facilities in electronic system			
R.73(2)	Medication preparation room or area (<i>at or nearby</i>)			
R.73(4)	Clinical hand washing facilities (<i>at or nearby</i>)			
R.73(3)	Toilet with hand washing facility for staff (<i>nearby</i>)			
R.122(2)	Call systems are kept in good repair and operating condition			
	R.43 Appropriate medical record system facilities			
	Medicine preparation room or area			
R.74(1)(a)	Locked cabinet for dangerous drug			
R.74(1)(b)	Work space for preparation of medication			
R.74(1)(c)	Sink with hand washing facilities			
R.74(2)	Refrigerator with thermometer and exclusively for pharmaceutical storage			
R.74(3)	No test reagents, general disinfectants, cleaning agents and similar products in this room or area			
	Examination and treatment room			
R.54	Doors size $\geq 1.2\text{m}$ & not swing into the corridors			
R.58	Adequate ceiling height (air condition $\geq 2.4\text{m}$, if not $\geq 3.0\text{m}$)			
R.79(1)(a)	Dimension $\geq 3.0\text{m}$			

PROVISION	ITEM	YES	NO	COMMENT
R.79(1)(a)	Area $\geq 11.1\text{m}^2$			
R.79(1)(b)(i)	Hand washing facility			
R.79(1)(b)(ii)	Examination light			
R.79(1)(b)(iii)	Storage for linen, supplies and equipment			
R.79(1)(b)(iv)	Examination & treatment couch			
R.79(1)(b)(v)	Screen or curtain for patient privacy			
R.79(2)(a),(b)	Located near nurses station or where patient care is provided or procedure is carried out			
R.49(3)(c)(v)	Contaminated equipment shall not be used for patients			
R.20	Resuscitation facilities			
8th Schedule (b)	Oxygen			
(c)	Ventilation assistance equipment (e.g. ambubag)			
(d)	ECG monitoring with cardiac defibrillator			
(e)	Intravenous therapy			
(f)	Laryngoscope and endotracheal tubes			
(g)	Suction equipment			
(h)	Urinary catheters			
(i)	Drugs (<i>Adrenaline, Atropine, Steroid, S.Bicarb</i>)			
R. 290(2)	First aid kits and eye wash facilities are readily available and conveniently located			
	Bleeding area			
R.282(f)	Separated bleeding area from work area			
R.54(1)	Door size $\geq 1.2\text{m}$ wide (<i>for patient care</i>)			
R.282(a)	Sufficient space to perform activities and work with efficiency and safety			
R.58	Adequate ceiling height (air condition $\geq 2.4\text{m}$, if not $\geq 3.0\text{m}$)			
R.291(1)(a)	Consumables and equipment for blood collection comply with 10 th Schedule (Appendix 1)			
1.	Consumables for blood collection			
	(a) disposable lancet			
	(b) disinfectant dressing			
	(c) material and supplies for the determination of haemoglobin concentration			

PROVISION	ITEM	YES	NO	COMMENT
	(d) blood collection plastic container including disposable needle			
	(e) test tube for sample collection			
	(f) label for blood containers, samples and records			
	(g) supplies for donor refreshment			
	(h) stationery and material for adequate documentation of blood donors and donations			
	(i) resuscitation drugs			
2.	Equipment for blood collection			
	(a) donor bed			
	(b) scale for weighing blood bag collected			
	(c) domestic scale for weighing donors			
	(d) miscellaneous equipment and surgical instrument, including scissors, forceps, sphygmomanometer, tourniquet, stethoscope, thermometer, glove, sharp instrument such as needle, syringe etc., container, hand sealer, tube stripper			
	(e) necessary equipment for donor refreshment			
	(f) resuscitation equipment or kit			
3.	Equipment for plasma collection			
	(a) plasmapheresis machine for collection of plasma from blood donors			
	(b) platelet-pheresis machine (apheresis) for collection of platelets direct from donors			
	(c) defibrillator for resuscitation of donors who collapse while attached to plasmapheresis/ apheresis machines			
R. 287(2)	UPS for plasmapheresis and apheresis			
R.284(2)	Space provided for acceptable movement of materials and personnel with minimal traffic and for relevant activities to be carried out			
	Donor recovery area/nourishment station or pantry			
R.282(f)	Separated donors recovery area from work area			
R.54(1)	Door size $\geq 1.2\text{m}$ wide (<i>for patient care</i>)			
R.282(a)	Sufficient space to perform activities and work with efficiency and safety			
R.58	Adequate ceiling height (air condition $\geq 2.4\text{m}$, if not $\geq 3.0\text{m}$)			
R.80(1)	Sink with hand washing facilities			
R.80(1)	Serving equipment (<i>between schedule meals</i>)			

PROVISION	ITEM	YES	NO	COMMENT
R.80(1)	Refrigerator			
R.80(1)	Storage cabinet			
R.80(2)	Source and preparation of ice used for patient service or treatment shall be clean and hygienic			
	Work/processing area			
R.282(d),(f)	Separated from reception area, bleeding area and donors recovery area			
R.282(a)	Sufficient space to perform activities and work with efficiency and safety			
R.284(2)	Space provided for acceptable movement of materials and personnel with minimal traffic and for relevant activities to be carried out			
R.283(1)	Washable surfaces			
R.282(b)	Adequate work bench space for handling, processing, testing samples and placement equipment and reagents			
R.283(2)	Where corrosive materials are used - surfaces and floor of corrosive-resistant materials.			
R.283(3)	No wooden surface in processing areas			
R.291(1)(b)	Consumables and equipment for blood bank laboratory work comply with 10 th Schedule (Appendix 2)			
1.	Consumables for blood bank laboratory work			
	(a) microtitre plate, test tube or tile and microscope slide			
	(b) reagent for blood grouping and compatibility testing			
	(c) test reagent and supplies for screening of transfusion transmissible infections			
	(d) disinfectant and detergent			
	(e) container for disposal of contaminated articles			
	(f) protective clothing and disposable glove			
	(g) timer			
	(h) squeeze bottle			
2.	Equipment for blood bank laboratory work			
	(a) bench centrifuge for separation of samples and serological testing			
	(b) analytical balance electronic			
	(c) microscope binocular or Maggie lamp			
	(d) 37 degree Celsius water bath			
	(e) refrigerator with temperature monitoring system			

PROVISION	ITEM	YES	NO	COMMENT
	(f) emergency generator, mechanical or solar			
	(g) voltage stabiliser			
	(h) container and coolant (or ice) for transportation of blood products			
	(i) plastic holder to hold blood bag			
	(j) laboratory thermometer			
	(k) autoclave			
R.291(1)(c)	Consumables and equipment for component preparation comply with 10 th Schedule (Appendix 3)			
	1. Consumables for component preparation			
	(a) double/triple/quadruple bag or pedi bag			
	(b) transfer bag			
	2. Equipment for component preparation			
	(a) refrigerated centrifuge recommended for premises handling more than 1000 donors per year			
	(b) plasma extractor			
	(c) hand sealer			
	(d) freezer (-40 degrees Celsius) with temperature monitoring system			
	(e) recommended:			
	(i) low temperature freezer (-35 degrees Celsius) for storage of cryoprecipitate, fresh frozen plasma (FFP) and plasma; and			
	(ii) ultra low temperature freezer (-70 degrees Celsius) for longer storage of blood components			
	(f) blast freezer for premises handling more than 1000 donors per year			
	(g) platelet agitator with or without incubator at 20 to 24 degrees Celsius			
	(h) docking instrument recommended			
R.287(1)	Adequate and stable electrical source for high precision equipment			
R.282(c)	Sink, water and electrical outlets located conveniently to the work area			
R.284(4)	Doors directly lead to the outside shall be sealed and used for emergency only			
	Office space			
R.282(k)	Separated office space from the work area			
	Store area			
R.282(i)	Storage facilities for documentation, data storage and data retrieval			

PROVISION	ITEM	YES	NO	COMMENT
R.291(1)	Adequate and appropriate consumables and equipment			
R.282(g)	Adequate store room for supplies, consumables, equipment			
	Clean utility room			
R. 75(1)	At least one room per nurses' station			
R. 75(1)	A counter and space for the storage			
R. 75(2)	No hand washing sink			
R. 75(3)	Air-conditioned room			
R.115	Clean linen storage separate from laundry			
	Soiled utility room			
R.76	At least one room per nurses' station			
R.76	Work counter			
R.76	Waste receptacle			
R.76	Soiled linen receptacle			
R.76	Washing equipment			
R.76	Clinical sink			
R. 81(2)	Double compartment sinks to clean utensil and equipment with adequate counter space on both sides and depth (<i>according to its function</i>)			
	Janitor's closet			
R.77(1)(a)	Sink (<i>preferably with a floor receptor with mixing taps</i>)			
R.77(1)(b)	Hook strip for mop handle			
R.77(1)(c)	Shelf for cleaning material			
R.77(1)(d)	Waste receptacle with impervious liner			
R.77(1)(e)	Hand washing facility			
R.77(2)	Adequate space for mop, bucket & cleaning equipment			
	Housekeeping			
R.93	Housekeeping services properly operated & maintained to provide a pleasant, safe and sanitary environment			
R.96	Availability & properly maintained equipment for cleaning			

PROVISION	ITEM	YES	NO	COMMENT
R.98	Cleaning compound and hazardous substance are labelled and stored in safe places			
R.100	No dry dusting and sweeping			
	Toilet and shower facilities			
R.54(2)	Clear opening for donors' toilet door $\geq 0.9\text{m}$ & not swing inward, neither into corridor			
R.427	Separate toilets for male and female staff			
R.56(2)	No carpet			
R.69(3), 290	Toilet for healthcare professional and staff			
R. 290(1)	Adequate and conveniently located toilets, showers and washbasin facilities for persons seeking the services			
	Staff facilities			
R. 426, 282(j)	Rest room or area with pantry (separate from work area)			
	Overall findings			
S.16(1)(a)	Complies with the building layout plan, design construction and specification to which the approval to establish or maintain relates			
S.16(1)(b)	Equipment, apparatus, instrument, material, article, sample or substance or any other thing found in the premises, or any matter connected therewith			
R.122(2)	Infrastructure and all equipment are kept in good repair and operating condition			
R.122(2)	Sterilizers are kept in good repair and operating condition (if available)			
	STANDARD & REQUIREMENT (DOCUMENTATION)			
	Organization & Management			
S. 62 & R.300	Transfusion committee - to advise the licensee or PIC on matter relating to blood transfusion & assist in investigation blood transfusion reaction			
R.11(2)	Plan of organization in writing (<i>specify the authority, responsibility and functions of each category of staff</i>)			
	Personnel			
R.281(1)	Under the supervision of a RMP with training and experience in blood bank or blood transfusion services			
R.281(2)	Categories and types of staff shall be in accordance with the scope and load of staff			
R.279	Person allowed to collect blood from donor			

PROVISION	ITEM	YES	NO	COMMENT
	- RMP with training and experience			
	- Registered MA with training and under supervision			
	- SRN with training and under supervision			
R.280	Person allowed to screen or process			
	- RMP experience in blood bank and transfusion services			
	- Technical staff with qualification, training and 2 years of experience in blood bank and transfusion services			
R.13(1)	All healthcare professional are registered with proper qualification, training & experience			
R.25(b)	Name and professional status of staff providing care or treatment			
S.2	Other allied health professional			
	Policies and standard operating procedures			
R.22, 292, 293, 296	Relevant written policies, standards, procedures and guidelines are available and accessible to all personnel			
R.293	Standard Operating Procedures relating to collection, handling, transportation, storage of blood, blood products, blood samples and blood transfusion			
R.292(2)	Standard Operating Procedures Manual for all tests and technical procedures			
R.296(3)	Guidelines on blood bank or blood transfusion laboratory safety (to personnel and environment)			
R.296(10)	Standard Operating Procedures on all safety activities of the blood bank and blood transfusion services and blood donation programme			
R.299	Criteria and standard for blood donor recruitment, selection and care (refer Code Of Ethics for blood donation and transfusion MOH)			
R.291(4)	Guidelines for the maintenance of laboratory equipments			
R.(2)(a)&(b)	Written policy available to all staff & review every 5 years			
	Clinical practice guidelines			
R.22(1),(2)	In accordance to the facilities and services provided			
R.49(6)	Infection control directives or guidelines			
	Records, registers, returns and books			
R.34	Staff register			
R.291(4)	Records of calibration, repairs and maintenance of laboratory equipments			
R.292(4)	Record on quality assessment tests for all the tests and technical procedures			

Blood Bank

PROVISION	ITEM	YES	NO	COMMENT
R.294	Records on blood donors including the name, address blood-group with Rh factor type, date, amount of blood taken and result of blood screening tests.			
R.296(6)	Record on all personnel are vaccinated and immunised against hepatitis and other diseases as deemed necessary by DG*			
R.296(7)	Health cards of all personnel (laboratory accidents, episodes of illness and immunisation status)			
R.299(5)	Adequate record systems for regular and safe donors			
	Program and activities on quality			
S.74(1),(2)	Information on quality programme and activities			
R.295	Quality assurance activities			
	Overall findings			
S.16(1)(c)	Complies with standards or requirements: books, records, policies, standard operating procedures, clinical practice guidelines or the management or related matters			

Comments:	
Recommendation:	
Prepared by:	Verified by:
(Name & Stamp)	(Name & Stamp)
Date :	Date: