Operations	Immunology
Procedure	Lot release Manual/virology live vaccines summary of product testing & release criteria - Appendix 7.2
Written	s22 & s22
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Appendix 7.2 Virology Live/Inactivated Vaccines - Summary of Product Testing & Release Criteria

Product / Vaccine name ARTG No.	WinLIMS product **number**	**Samples required by TGA**		**Summary of the current testing program and criteria for market release.**
		Initial	Further	
Cervarix 126115 (vial) 126114 (PFS)	 209756 209755	5	1	**Testing Summary:** Testing under development. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency ELISA, vaccine protocol check, and protocol potency (mouse RP).* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Ervevax 68713 69211 68714	NS*	20	3	**Testing Summary:** Currently not marketed in Australia. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, vaccine protocol check, and protocol potency.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Gardasil 124408 (vial) 124410 (PFS)	 207386 207388	5	1	**Testing Summary:** Testing under development. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency ELISA, vaccine protocol check, and protocol potency ELISA.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.

Product / Vaccine name **ARTG No.**	WinLIMS product **number**	**Samples required by TGA**		**Summary of the current testing program and criteria for market release.**
		Initial	Further	
IMOJEV 162215	264911	5	1	**Testing Summary:** Currently not marketed in Australia. Testing to be developed when it is. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency, vaccine protocol check, and protocol potency*. Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
IPOL 47217	100092	3	1	**Testing Summary:** Testing of the three components on released product with satisfactory *sample packaging* is sufficient to show consistency of production. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency ELISA, vaccine protocol check, and protocol potency ELISA*. Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Jespect 150602	255688	3	1	**Testing Summary:** Not presently tested. Release testing performed by European Regulatory Agency. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, vaccine protocol check, and protocol potency (mouse immunogenicity)*. Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Measles contract testing for WHO	LVWHOM	unspecified		**Testing Summary:** This product is exempt from lot release procedures. The product is tested when received from WHO. 1. Appearance, Cold-chain max and min and sample potency and thermostability. 2. THIS PRODUCT IS EXEMPT FROM LOT RELEASE PROCEDURES, the product is not market released, nor are protocols received.

Product / Vaccine name **ARTG No.**	WinLIMS product **number**	**Samples required by TGA**		**Summary of the current testing program and criteria for market release.**
		Initial	Further	
Merieux Inactivated Rabies Vaccine (MIRV) 26675	90977	3	1	**Testing Summary:** Not presently tested. Release testing performed by European Regulatory Agency. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, vaccine protocol check, and protocol potency.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Meruvax II 10495	38536	20	3	**Testing Summary:** Not currently marketed. Testing of the Rubella component on released product with satisfactory *sample packaging* is sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency and thermostability, vaccine protocol check, and protocol potency and thermostability.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
MMR II 39380	NS*	20	0	**Testing Summary:** Not currently marketed. Testing of the 3 components on released product with satisfactory *sample packaging* is sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency and thermostability, vaccine protocol check, and protocol potency and thermostability.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.

Product / Vaccine name **ARTG No.**	WinLIMS product **number**	**Samples required by TGA**		**Summary of the current testing program and criteria for market release.**
		Initial	Further	
Oral Polio Vaccine (OPV) 13046 (vial) 96510 (tube)	NS*	4	4	**Testing Summary:** Not currently marketed. Testing of the 3 components on released product with satisfactory *sample packaging* is sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency, vaccine protocol check, and protocol potency.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Priorix 97843 (ampoule) 97842 (PFS^) 97841	169211 169208 169207	20	3	**Testing Summary:** Testing of the 3 components on released product with satisfactory *sample packaging* is sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency and thermostability, vaccine protocol check, and protocol potency and thermostability.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Priorix-Tetra 107284	NS*	20	3	**Testing Summary:** Not currently marketed. Testing of the 4 components on released product with satisfactory *sample packaging* will be sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency and thermostability, vaccine protocol check, and protocol potency and thermostability.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.

Product / Vaccine name **ARTG No.**	WinLIMS product **number**	**Samples required by TGA**		**Summary of the current testing program and criteria for market release.**
		Initial	Further	
ProQuad 126153 (vial) 126157 (PFS)	NS*	20	3	**Testing Summary:** Not currently marketed. Testing of the 4 components on released product with satisfactory *sample packaging* will be sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency and thermostability, vaccine protocol check, and protocol potency and thermostability.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Rabipur 100582	175363	5	1	**Testing Summary:** Not presently tested. Release testing performed by European Regulatory Agency. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, vaccine protocol check, and protocol potency.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Rotarix 116532 146776 146776	196453 250494 250495	20	3	**Testing Summary:** Testing of the rotavirus component on released product with satisfactory *sample packaging* is sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency and thermostability, vaccine protocol check, and protocol potency and thermostability.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.

Product / Vaccine name **ARTG No.**	WinLIMS product **number**	**Samples required by TGA**		**Summary of the current testing program and criteria for market release.**
		Initial	Further	
RotaTeq 120245	201739	20	3	**Testing Summary:** Testing of the rotavirus component on released product with satisfactory *sample packaging* is sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency and thermostability, vaccine protocol check, and protocol potency and thermostability.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Stamaril 58571	125206	3	0	**Testing Summary:** Not presently tested. Release testing performed by European Regulatory Agency **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, vaccine protocol check, and protocol potency.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Synagis 68290 100mg	LVP009	0	0	**Testing Summary:** F Protein ELISA assay assessed by TGA. As product is used only a limited quantity and is very costly further validation and testing is not justified. No samples received by TGA. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *vaccine protocol check.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.

Product / Vaccine name ARTG No.	WinLIMS product number	Samples required by TGA		Summary of the current testing program and criteria for market release.
		Initial	Further	
Varilrix 71008 (vial) 71007 (PFS)	137123 137115	20	3	**Testing Summary:** Testing of the Varicella component on released product with satisfactory *sample packaging* is sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency and thermostability, vaccine protocol check, and protocol potency and thermostability.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Varivax Refrigerated 90140 (vial) 115008 (PFS)	160164 194648	20	3	**Testing Summary:** Testing of the Varicella component on released product with satisfactory *sample packaging* is sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency, vaccine protocol check, and protocol potency.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.
Zostavax 130241 (vial) 130299 (PFS)	215093 215081	20	3	**Testing Summary:** Testing of the Varicella component on released product with satisfactory *sample packaging* is sufficient to show consistency of production. Live viral vaccines may be tested during the shelf-life due to the nature of the product. **Criteria for market release:** 1. Satisfactory company manufacture and testing protocols. 2. Acceptable *sample packaging, appearance, labelling, market quantity, cold-chain max and minimum, shipping conditions, sample potency, vaccine protocol check, and protocol potency.* Release if there are no concerns with 1 & 2 above. Appropriate follow up with the company is required if there are any concerns with results from 1 & 2 above.

* NS = Not Supplied
^PFS = Prefilled Syringe