

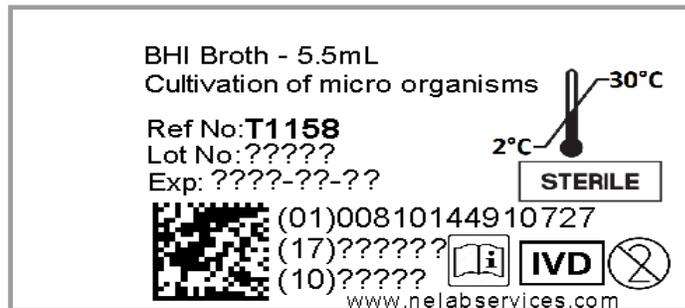
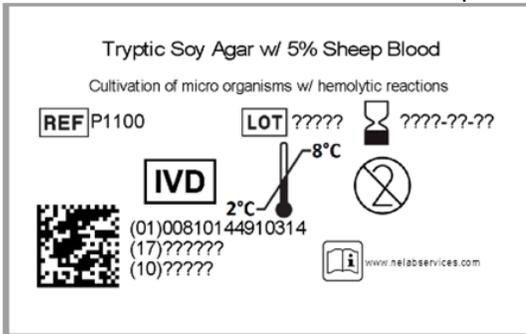
Product Change Notification

From: Northeast Laboratory Services, Quality Department

Date: 2023-09-18

Dear Valued Customer:

Northeast Laboratory Services (NEL) is sending this notification to alert you of a change regarding new labels for In-Vitro Diagnostic Products (IVD). Per FDA guidelines for IVD use devices, labels must contain a scannable and human readable unique device identifier (UDI). To meet these requirements, a scannable and human readable data matrix code will be included with each lot of manufactured products and will look similar to the examples below:



The following NEL part numbers will be affected by this change:

CHRP0015	P1122	P1405	P1515	P1662	P5060				
P1050	P1130	P1410	P1550	P1675					
P1070	P1150	P1491	p1550-1	P1700					
P1100	P1160	P1497	P1551	P3100					
P1102	P1250	P1499	P1640	P3140					
P1103	P1301	P1500	P1651	P5000					
P1120	P1350	P1507	P1660	P5010					
P1050	P1400	P1510	P1660-2	P5050					
T1050	T1300	T1479	T1549	T1627	T1645	T1671	T1760	T1850	T2003
T1150	T1350	T1500	T1550	T1630	T1650	T1678	T1761	T1855	T2005
T1158	T1455	T1501	T1552	T1633	T1651	T1701	T1765	T1856	T2009
T1161	T1456	T1502	T1558	T1635	T1655	T1720	T1766	T1865	T2013
T1172	T1462	T1521	T1560	T1638	T1656	T1730	T1780	T1950	T2020
T1184	T1464	T1540	T1620	T1639	T1657	T1750	T1800	T1951	T2050
T1186	T1470	T1546	T1623	T1640	T1660	T1751	T1805	T1952	T2060
T1250	T1475	T1548	T1624	T1641	T1662	T1753	T1825	T2000	T2100
T2107	T3013	MGHT-STR	X1100	X1150	X1225	X1250	X1260	X1265	X1500

This change follows FDA guidelines for IVD products. This change will go into effect for productions occurring on and after September 20, 2023.

We are confident that this change will not affect the integrity of our final products. If you have any questions, please reach out to your Customer Experience Representative or our Quality Team.

Sincerely,

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