CONSIDERING THAT

1. During the 71st General Session of WOAH in May 2003, the Assembly adopted Resolution No. XXIX endorsing the principle of validation and certification of diagnostic assays for animal diseases by WOAH, and giving a mandate to the Director General to set up the specific standard procedures to be used before the final decision on the validation and certification of a diagnostic kit is taken by the World Assembly of Delegates,

2. The Resolution has established that ‘fitness for purpose’ should be used as a criterion for validation,

3. The aim of the WOAH procedure for the registration of diagnostic kits is to establish a register of recognised kits for WOAH Members and for diagnostic kit manufacturers,

4. WOAH Members need kits that are known to be validated according to WOAH standards to enhance confidence in kits,

5. The WOAH Register of recognised diagnostic kits provides greater transparency and clarity of the validation process and a means for recognising those manufacturers that validate and certify tests marketed in kit format,

6. According to WOAH Standard Operating Procedure, registration of diagnostic kits included in the Register has to be renewed every 5 years,

7. During the 74th General Session in May 2006, the Assembly adopted Resolution No. XXXII on the importance of recognising and implementing WOAH standards for the validation and registration of diagnostic assays by Members,

8. The Validation Studies Abstracts are available as Annexes 18 and 19 of the report of the Biological Standards Commission meeting of 5–9 February 2024 for the Genelix™ ASFV Real-time PCR Detection kit, and Sentinel® ASFV Antibody Rapid Test,

9. There are no Validation Studies Abstract for the Avian Influenza Antibody Test Kit (registration number 20080203), and the Newcastle Disease Virus Antibody Test Kit (registration number 20140109) as these are 5-year renewals without any additional data evaluation or changes.

THE ASSEMBLY

DECIDES THAT

1. In accordance with the WOAH procedure for registration of diagnostic kits and the recommendations of the Biological Standards Commission, the Director General proposes the inclusion in the WOAH Register of the following new terrestrial diagnostic kits certified by WOAH for a period of 5 years:
<table>
<thead>
<tr>
<th>Name of the diagnostic kit</th>
<th>Name of the Manufacturer</th>
<th>Fitness for purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genelix™ ASFV Real-time PCR Detection kit</td>
<td>Sanigen Co., Ltd (Korea [Rep. of])</td>
<td>The Genelix™ ASFV Real-time PCR Detection kit is a product that qualitatively detects and confirms the diagnosis of African swine fever virus (ASFV) using a real-time PCR detection system in whole blood, serum, and tissues of swine suspected of being infected with ASFV.</td>
</tr>
<tr>
<td>Sentinel® ASFV Antibody Rapid Test</td>
<td>Excelsior Biosystem Incorporation (Chinese Taipei)</td>
<td>The Sentinel® ASFV antibody test is a qualitative lateral flow assay that detects African Swine Fever Virus (ASFV) antibodies in serum associated with current infection or an immune response to previous exposure in an individual pig, group of pigs or defined population of pigs. For use in conjunction with other tests or diagnostic procedures, as an aid in diagnosis or other clinical or epidemiological assessments.</td>
</tr>
</tbody>
</table>

2. In accordance with the WOAH procedure for the registration of diagnostic kits and the recommendations of the Biological Standards Commission, the Director General proposes to renew for a period of an 5 additional years the inclusion in the WOAH Register of the following diagnostic kits certified by WOAH as validated as fit for purpose:

<table>
<thead>
<tr>
<th>Name of the diagnostic kit</th>
<th>Name of the Manufacturer</th>
<th>Fitness for purpose</th>
</tr>
</thead>
</table>
| Avian Influenza Antibody Test Kit (registration number 20080203)| BioChek (UK) Ltd                                  | Fit for serological diagnosis of type A avian influenza in chickens (specific to IgG in serum) and for the following purposes:  
1. To demonstrate historical freedom from infection in a defined population (country/zone/compartment/herd);  
2. To demonstrate re-establishment of freedom after outbreaks in a defined population (country/zone/compartment/herd);  
3. To confirm diagnosis of suspect or clinical cases;  
4. To estimate prevalence of infection to facilitate risk analysis in non-vaccinated populations (surveys/herd health schemes/disease control);  
5. To determine immune status in individual animals or populations (post-vaccination).  
**The original registration Resolution No.27 was adopted in May 2008 by the World Assembly of the OIE/WHO Delegates** |
| Newcastle Disease Virus Antibody Test Kit (registration number 20140109)) | BioChek (UK) Ltd                                  | Fit to detect Newcastle disease virus specific IgG antibodies in chicken sera and for the following purposes:  
1. To demonstrate historical freedom from infection in a defined population (country/zone/compartment/flock); |
2. To determine immune status in individual animals or populations (post-vaccination);
3. To monitor infection or disease in unvaccinated populations;
4. To estimate prevalence of infection to facilitate risk analysis in non-vaccinated populations (surveys/flock health schemes/disease control).

**The original registration Resolution No. 29 was adopted in May 2014 by the World Assembly of the OIE/WOAH Delegates**