FOR ANIMAL USE ONLY

INTERTEST® Avian PPD Tuberculin
Reg. No. G3754 (Act 36/1947)
Namibia Reg. No. V07/24.9/374 NS0

INDICATIONS
Intertest® Avian PPD Tuberculin is used for diagnosis of avian tuberculosis and comparative tuberculin test in cattle and other domestic animals.

NOTE
Tuberculosis is a controlled disease in terms of the Animal Diseases Act (Act 35/1984). In terms of the act it is stipulated that:
(1) Any occurrence or suspected occurrence of tuberculosis has to be reported immediately to the local State Veterinarian.
(2) A tuberculin test may be carried out only by a state veterinary officer, an authorised person or a veterinarian. All tuberculin test results have to be communicated in writing to the State Veterinarian who is responsible for the determination of the disease status of an animal with regards to tuberculosis.
(3) Infected, suspect and contact animals shall be isolated, tested, marked and slaughtered as determined by the State Veterinarian.

COMPOSITION
Intertest® Avian PPD Tuberculin is a purified protein derivative (PPD) of *Mycobacterium avium* strain D_4 cultures. It contains no live bacteria.
1 mℓ of the solution contains 25 000 IU and a maximum of 0,5 % of phenol as preservative.

STORAGE
- Store between 2 °C and 8 °C.
- Do not freeze.
- Protect from light.
- Do not use the product after the expiry date.
- After broaching the vial, use immediately.

WARNINGS
- **Withdrawal period**: None
- Acutely sick animals are to be exempted from administration of **Intertest® Avian PPD Tuberculin**.
- In order to prevent inflammatory reactions the test should be administered aseptic.
- In case of infections with mycobacteria of other species, non-specific reactions may result. In order to differentiate between avian tuberculosis and bovine tuberculosis a comparative tuberculosis test should be performed.
- The comparative test for bovine tuberculosis should be administered at the earliest 6 weeks after previous administration of **Intertest® Avian PPD Tuberculin** to prevent false results. Similar waiting periods should be observed before a post-examination in poultry.
- To prevent false negative results, animals which are treated, e.g. with corticosteroids or ACTH (Adrenocorticotropic hormone), are to be exempted from testing with **Intertest® Avian PPD Tuberculin**. After the administration of live viral vaccines false negative results cannot be ruled out.
- On rare occasions latently infected animals or sensitised animals may show allergic or anaphylactic reactions when injected with **Intertest® Avian PPD Tuberculin**.

- KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.
- Although this product has been extensively tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS
Although **Intertest® Avian PPD Tuberculin** does not contain living organisms, it is recommended to dispose waste material derived from the product according to local waste disposal regulations.

DOSAGE AND DIRECTIONS FOR USE - USE ONLY AS DIRECTED
One dose of 0,1 mℓ contains 2 500 IU.
The correct placement of the injection is indicated by a pea-like swelling at the site of injection.

Comparative tuberculin test
- In bovines with suspect results a comparative tuberculin test should be done with bovine and avian tuberculin simultaneously administered at the earliest 6 weeks after a previous administration of tuberculin.
- The execution of the comparative tuberculin test follows in the same manner as the process of bovine tuberculin testing. The 2 intracutaneous injections should be undertaken either on one side (in that case bovine tuberculin above and avian tuberculin below) or on opposite sides of the body at corresponding positions (on the neck at the ridge of the shoulder blade). In the latter case the possible occurrence of clinical symptoms at the points of injection (specifically a parallel infection of the regional lymphatic nodes and lymphatic vessels) can be defined more clearly.
- 0,1 mℓ of bovine tuberculin with 5 000 IU and 0,1 mℓ avian tuberculin with 2 500 IU should be injected into a fold of skin. The points of injection are to be marked. This can be accomplished most practically by shaving the skin in an area of approximately 8 to 10 cm in length and approximately 2 to 3 cm in width. In these areas no thickening should occur. At both points of injection, the thickness of the fold of the skin is to be measured (e.g. Hauptner-calliper) and noted. It is important to see to it that the tuberculin is injected strictly intradermal and not subcutaneously. In addition, care should be taken that no vaccine flows out of the injection site. In order to check the correct positioning of the intradermal injection, it has proven prudent to check the point of injection with the tip of the finger for the presence of a pea-like swelling.
- The result of the tuberculin tests should not be read and evaluated earlier than 72 hours and not later than 96 hours after the injection of the tuberculin. During the reading, particular note should be taken of the careful measuring of the thickness of the skin at the point of injection. The evaluation of the tuberculin reaction follows through comparison of the reactions obtained with bovine and avian tuberculin. The evaluation is to be executed taking cognisance of the clinical symptoms as presented at the point of injection, i.e. pain, a doughy consistence, exudation and necrosis, particularly however on the basis of the actual precisely measured increase in thickness of the skin. An evaluation undertaken solely on the basis of palpation is in no way sufficient.

Interpretation of reactions
The interpretation of reactions shall be based on clinical observations and the recorded increase in skin-fold thickness at the sites of injection 72 hours after injection of tuberculin.

The following key is to be used as a guideline for evaluation:

Bovine minus avian tuberculin	Thickness of skin (difference in mm)	Diagnosis
Positive result	More than 4,0 mm	Positive
	2,1 to 4,0 mm	Suspect
	Up to 2,0 mm	Negative
Negative result	Increase which is less than or equal to the reaction at the site of avian injection and absence of clinical signs.	Negative

1. If clear clinical symptoms occur, even with a very small margin in bovine tuberculin, the presence of a bovine tuberculosis infection is possible.
2. Any retest should be performed in accordance with the local or national control programme standard.

PRESENTATION
Boxes with vials each containing 2 mℓ (20 doses)
Boxes with carpoules each containing 1,8 mℓ (18 doses)

REGISTRATION HOLDER
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SLEGS VIR DIEREGEBRUIK

INTERTEST® Avian PPD Tuberculin
Reg. Nr. G3754 (Wet 36/1947)
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INDIKASIES
Intertest® Avian PPD Tuberculin word gebruik vir die diagnose van hoendertuberkulose en vergelykende tuberkulientoetse in beeste en ander huishoudelike soogdiere.

NOTA
Tuberkulose is ’n beheerde siekte in terme van die Wet op Dieresiektes (Wet 35/1984). In terme van die wet word dit bepaal dat:
(1) Enige voorkoms of vermoedelike voorkoms van tuberkulose onmiddellik aan die plaaslike Staatsveearts gerapporteer moet word.
(2) ’n Tuberkulientoets net gedoen mag word deur ’n veterinêre staatsbeampte, ’n persoon daartoe gemagtig of ’n veearts. Alle tuberkulientoetsresultate moet skriftelik aan die Staatsveearts, wat verantwoordelik is vir die bepaling van die siektestatus van die dier ten opsigte van tuberkulose, voorsien word.
(3) Die Staatsveearts sal bepaal watter besmette, vatbare of kontakdiere geïsoleer, getoets, gemerk of
geslag moet word.

SAMESTELLING
Intertest® Avian PPD Tuberculin is ’n gesuiwerde proteïenderivaat van *Mycobacterium avium* stam D_4 kulture.Dit bevat geen lewende bakterieë nie.
1 mℓ van die oplossing bevat 25 000 IE. en ’n maksimum van 0,5 % fenol as preserveermiddel.

BERGING
- Berg tussen 2 °C en 8 °C. Beskerm teen sonlig. Moet nie vries nie.
- Moenie die produk na die vervaldatum gebruik nie.
- Gebruik onmiddellik nadat flessie oopgemaak is.

WAARSKUWINGS
- **Onttrekkingsperiode:** Geen.
- Diere wat akuut siek is moet vrygestel word van toediening met **Intertest® Avian PPD Tuberculin**.
- Om inflammatoriese reaksies te voorkom moet die toets asepties uitgevoer word.
- In geval van infeksies met mikobakterieë van ander spesies, mag nie-spesifieke reaksies voorkom. Om tussen hoendertuberkulose en beestuberkulose te onderskei behoort ’n vergelykende toets gedoen te word.
- Die vergelykende toets vir beestuberkulose behoort, op die vroegste, 6 weke na vorige toediening van **Intertest® Avian PPD Tuberculin** gedoen te word om ‘n vals resultaat te vermy. 'n Soortgelyke wagperiode moet nagekom word vir 'n herevaluering in pluimvee.
- Om vals negatiewe resultate te verhoed, moet diere wat behandel is met, bv. kortikosteroïede of AKTH (Adrenokortikotropiese hormoon), vrygestel word van toetsing met **Intertest® Avian PPD Tuberculin**. Na die toediening van lewende virale entstowwe kan vals negatiewe resultate nie buite rekening gelaat word nie.
- In uitsonderlike gevalle kan diere wat aangesteek het of gevoelige diere ’n allergiese reaksie of anafilaktiese reaksies toon wanneer ingespuit word met **Intertest® Avian PPD Tuberculin**.

- HOU BUITE BEREIK VAN KINDERS, ONINGELIGTE PERSONE EN DIERE.
- Alhoewel hierdie produk breedvoerig onder ’n wye verskeidenheid toestande getoets is, mag dit faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg ’n veearts en verwittig die registrasiehouer**.**

VOORSORGMAATREëLS
Alhoewel **Intertest® Avian PPD Tuberculin** geen lewende organismes bevat nie, word dit tog aanbeveel dat alle afvalmateriaal volgens plaaslike afvalbestuursregulasies vernietig word.

DOSIS EN GEBRUIKSAANWYSINGS - GEBRUIK SLEGS SOOS AANGEDUI
Een dosis is 0,1 mℓ wat 2 500 IE bevat.
'n Korrekte toediening word aangedui deur die ontstaan van 'n swelsel van bykans ertjiegrootte by die plek van inspuiting.

Vergelykende tuberkulientoets
- In beeste met verdagte resultate behoort 'n vergelykende toets, met bees- en hoendertuberkulien gelyktydig toegedien, op die vroegste, 6 weke na vorige toediening van tuberkulien, gedoen word.
- Die uitvoering van die vergelykende tuberkulientoets volg dieselfde metode as vir beestuberkulien- toetsing. Die 2 intradermale inspuitings behoort of aan dieselfde kant (in hierdie geval hoendertuberkulien bo en beestuberkulien onder), of op dieselfde plek maar aan teenoorgestelde kante van die liggaam (op die nek by die rif van die bladbeen) toegedien te word. In laasgenoemde geval kan die moontlike voorkoms van kliniese tekens by die plek van inspuiting ('n parallelle infeksie van die streekslimfknope en limfvate) duidelik gesien word.
- 0,1 mℓ van beestuberkulien 5 000 IE en 0,1 mℓ hoendertuberkulien 2 500 IE. moet in 'n vou van die vel ingespuit word. Die plek van inspuiting moet gemerk word. Die maklikste metode is deur die vel in die gebied (omtrent 8 tot 10 cm in lengte en omtrent 2 tot 3 cm in breedte) te skeer. In die gebied moet geen verdikking van die vel of ander veranderinge voorkom nie. By albei plekke van inspuiting moet die dikte van die vou van die vel gemeet word (bv. Hauptner-calliper) en die lesings gedokumenteer word. Dit is belangrik dat die tuberkulien intradermaal ingespuit word en nie onderhuids nie. Sorg moet ook gedra word dat geen tuberkulien by die toedieningsplek uitvloei nie. Om die presiese plek van toediening van die intradermale inspuiting te bepaal, moet die toedieningsplek met die punt van die vinger getoets word vir 'n ertjiegrootte swelsel.
- Die resultaat van die tuberkulientoets moet nie vroeër as 72 uur en nie later as 96 uur na die toediening van die tuberkulien gelees en geëvalueer word nie. Die evaluering van die tuberkulienreaksie geskied deur die reaksies verkry met bees- en hoendertuberkulien te vergelyk. Die evaluering moet ook die kliniese tekens wat gevind word by die punte van inspuiting d.w.s. pyn, 'n deegagtige konsistensie, eksudasie en nekrose in ag neem, maar veral gedoen word op grond van die presiese gemete toename in veldikte. 'n Berekening wat slegs op betasting gedoen is, is nie voldoende nie. Tydens die lesing van die dikte van die vel by die punte van toediening, moet die veldikte noukeurig bepaal en gedokumenteer word.

<u>Evaluering</u>
Die resultate van die **Intertest® Avian PPD Tuberculin** toets moet gelees en geëvalueer word 72 uur na die toediening van die tuberkulien.

Die volgende moet as ‘n gids vir berekening gebruik word:

Bees- minus hoendertuberkulien	Dikte van die vel (verskil in mm)	Diagnose
Positiewe resultaat	Meer as 4,0 mm	Positief
	2,1 tot 4,0 mm	Verdag
	Tot 2,0 mm	Negatief
Negatiewe resultaat	Toename wat minder as of gelyk aan die reaksie is op die plek van hoenderinspuiting en die afwesigheid van kliniese tekens.	Negatief

1. As duidelike kliniese simptome voorkom, selfs met 'n baie klein verskil by die beestuberkulien, is die teenwoordigheid van beestuberkulose moontlik.
2. Enige hertoets moet uitgevoer word in ooreenstemming met die plaaslike beheerprogramstandaarde.

AANBIEDING
Kartonhouers met flessies wat elk 2 mℓ (20 dosisse) bevat
Kartonhouers met karpules wat elk 1,8 mℓ (18 dosisse) bevat

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