

Clinical studies

Study	Reason for exclusion
Abdollahi A, Shoar S, Nayyeri F et al. (2012) Diagnostic Value of Simultaneous Measurement of Procalcitonin, Interleukin-6 and hs-CRP in Prediction of Early-Onset Neonatal Sepsis. Mediterranean journal of hematology and infectious diseases 4(1): e2012028	- Early-onset neonatal infection
Aboud, M.I.; Waise, M.M.A.; Shakerdi, L.A. (2010) Procalcitonin as a marker of neonatal sepsis in intensive care units. Iranian Journal of Medical Sciences 35(3): 205-210	- Study design does not match those specified in the protocol [Case-control]
Adib, M., Bakhshiani, Z., Navaei, F. et al. (2012) Procalcitonin: A reliable marker for the diagnosis of Neonatal sepsis. Iranian Journal of Basic Medical Sciences 15(2): 777-782	- Case-control study
Ahmed, Ejaz; Rehman, Abdur; Ali, Muhammad Asghar (2017) Validation of serum C-reactive protein for the diagnosis and monitoring of antibiotic therapy in neonatal sepsis. Pakistan journal of medical sciences 33(6): 1434-1437	- Study design does not match those specified in the protocol
Al-Zwaini, E J (2009) C-reactive protein: a useful marker for guiding duration of antibiotic therapy in suspected neonatal septicaemia?. Eastern Mediterranean health journal = La revue de sante de la Mediterranee orientale = al-Majallah al-sihhiyah li-sharq al-mutawassit 15(2): 269-75	- Reference standard in study does not match that specified in protocol [Suspected infection]
Ammo, K. and Salacity, G. (2008) CRP and ESR as a diagnostic marker in detection of neonatal sepsis. Pakistan Paediatric Journal 32(1): 15-22	- Not possible to calculate a contingency table from the data specified in the protocol
Ang, A T; Ho, N K; Chia, S E (1990) The usefulness of CRP and I/T ratio in early diagnosis of infections in Asian newborns. The Journal of the Singapore Paediatric Society 32(34): 159-63	- Reference standard in study does not match that specified in protocol [Positive blood, CSF or urine culture]
Armanian, A.-M.; Farajollahi, M.; Salehimehr, N. (2019) Positive Culture Samples of Infants with Neonatal Infections in a Tertiary Neonatal Center in Isfahan, Iran. Archives of Iranian medicine 22(11): 659-662	- Outcome to be predicted does not match that specified in the protocol <i>Antibiotic susceptibility</i>
Auriti, Cinzia, Fiscarelli, Ersilia, Ronchetti, Maria Paola et al. (2012) Procalcitonin in detecting neonatal nosocomial sepsis. Archives of disease in childhood. Fetal and neonatal edition 97(5): f368-70	- Outcome to be predicted do not match that specified in the protocol [Reports number with suspected infection and with confirmed infection but statistical outcomes are for both groups combined]
Aydemir, C, Aydemir, H, Kokturk, F et al. (2018) The cut-off levels of procalcitonin and C-reactive protein and the kinetics of mean platelet volume in preterm neonates with sepsis. BMC pediatrics 18(1): 253	- Study design does not match those specified in the protocol [Case control]

Bach, P.R., Davis, B.W., Loughmiller, D. et al. (2007) C-reactive protein (CRP) in neonates: Comparing VITROS slide and high-sensitivity CRP methods [3]. <i>Clinical Chemistry</i> 53(11): 1979-1981	- Article commentary
Ballot, Daynia E, Perovic, Olga, Galpin, Jacky et al. (2004) Serum procalcitonin as an early marker of neonatal sepsis. <i>South African medical journal = Suid-Afrikaanse tydskrif vir geneeskunde</i> 94(10): 851-4	- Early-onset neonatal infection
Benitz, W E, Han, M Y, Madan, A et al. (1998) Serial serum C-reactive protein levels in the diagnosis of neonatal infection. <i>Pediatrics</i> 102(4): e41	- Reference standard in study does not match that specified in protocol [Blood, CSF or urine culture]
Billetop, A., Grant, K., Beasmore, J. et al. (2019) Clinical evaluation of point-of-care testing for wide-range C-reactive protein (wr-CRP) in neonates with suspected sepsis. <i>Journal of Laboratory Medicine</i> 43(3): 135-140	- Early-onset neonatal infection
Bohnhorst, Bettina, Lange, Matthias, Bartels, Dorothee B et al. (2012) Procalcitonin and valuable clinical symptoms in the early detection of neonatal late-onset bacterial infection. <i>Acta paediatrica (Oslo, Norway : 1992)</i> 101(1): 19-25	- Reference standard in study does not match that specified in protocol [Blood, CSF or urine culture]
Bressan, Silvia, Andreola, Barbara, Cattelan, Francesca et al. (2010) Predicting severe bacterial infections in well-appearing febrile neonates: laboratory markers accuracy and duration of fever. <i>The Pediatric infectious disease journal</i> 29(3): 227-32	- Reference standard in study does not match that specified in protocol [Blood, CSF, urine or stool culture or any aspirated fluid]
Brown, Jennifer Valeska Elli, Meader, Nicholas, Cleminson, Jemma et al. (2019) C-reactive protein for diagnosing late-onset infection in newborn infants. <i>The Cochrane database of systematic reviews</i> 1: cd012126	- Systematic review. Reference list checked for possible includes [1 article ordered for full text review]
Brown, J.V.E., Meader, N., Wright, K. et al. (2020) Assessment of C-Reactive Protein Diagnostic Test Accuracy for Late-Onset Infection in Newborn Infants: A Systematic Review and Meta-analysis. <i>JAMA Pediatrics</i> 174(3): 260-268	- Systematic review. Reference list checked for possible includes
Burgoine, K., Ikiror, J., Naizuli, K. et al. (2019) Reagent Strips as an Aid to Diagnosis of Neonatal Meningitis in a Resource-limited Setting. <i>Journal of Tropical Pediatrics</i> 65(1): 9-13	- Reference standard in study does not match that specified in protocol [Leukocyte count, protein and glucose]
Cetinkaya, M, Ozkan, H, Koksall, N et al. (2009) Comparison of serum amyloid A concentrations with those of C-reactive protein and procalcitonin in diagnosis and follow-up of neonatal sepsis in premature infants. <i>Journal of perinatology : official journal of the California Perinatal Association</i> 29(3): 225-31	- Outcome to be predicted do not match that specified in the protocol [Probable sepsis, not culture confirmed]
Chacha, Flora, Mirambo, Mariam M, Mushi, Martha F et al. (2014) Utility of qualitative C- reactive protein assay and white blood cells counts in the diagnosis of neonatal septicaemia at Bugando Medical Centre, Tanzania. <i>BMC pediatrics</i> 14: 248	- Outcome to be predicted do not match that specified in the protocol [Majority of babies have early onset neonatal infection]

Chan, D K and Ho, L Y (1997) Usefulness of C-reactive protein in the diagnosis of neonatal sepsis. Singapore medical journal 38(6): 252-5	- Reference standard in study does not match that specified in protocol [Positive blood or CSF cultures or joint aspirate]
Chan, Kathy Y Y, Lam, Hugh S, Cheung, Hon M et al. (2009) Rapid identification and differentiation of Gram-negative and Gram-positive bacterial bloodstream infections by quantitative polymerase chain reaction in preterm infants. Critical care medicine 37(8): 2441-7	- Not used in current practice
Chen, Hsiu-Lin, Hung, Chih-Hsing, Tseng, Hsing-I et al. (2009) Circulating chemokine levels in febrile infants with serious bacterial infections. The Kaohsiung journal of medical sciences 25(12): 633-9	- Reference standard in study does not match that specified in protocol [Positive blood, CSF or urine culture]
Chiesa, C, Panero, A, Rossi, N et al. (1998) Reliability of procalcitonin concentrations for the diagnosis of sepsis in critically ill neonates. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 26(3): 664-72	- Study design does not match those specified in the protocol [Case-control for late-onset]
Choi, Yoonjung, Saha, Samir K, Ahmed, A S M Nawshad Uddin et al. (2008) Routine skin cultures in predicting sepsis pathogens among hospitalized preterm neonates in Bangladesh. Neonatology 94(2): 123-31	- Study design does not match those specified in the protocol
Da Silva, O; Ohlsson, A; Kenyon, C (1995) Accuracy of leukocyte indices and C-reactive protein for diagnosis of neonatal sepsis: a critical review. The Pediatric infectious disease journal 14(5): 362-6	- Systematic review. Reference list checked for possible includes [2 articles ordered for full-text review]
Dai, Ji, Jiang, Wenjie, Min, Zhigang et al. (2017) Neutrophil CD64 as a diagnostic marker for neonatal sepsis: Meta-analysis. Advances in clinical and experimental medicine : official organ Wroclaw Medical University 26(2): 327-332	- Systematic review. Reference list checked for possible includes
Davis, Jonathan, Christie, Sharon, Fairley, Derek et al. (2015) Performance of a Novel Molecular Method in the Diagnosis of Late-Onset Sepsis in Very Low Birth Weight Infants. PloS one 10(8): e0136472	- Reference standard in study does not match that specified in protocol
Diar, H A, Nakwa, F L, Thomas, R et al. (2012) Evaluating the QuikRead C-reactive protein test as a point-of-care test. Paediatrics and international child health 32(1): 35-42	- Study does not contain any relevant index tests
Dillenseger, Laurence, Langlet, Claire, Iacobelli, Silvia et al. (2018) Early Inflammatory Markers for the Diagnosis of Late-Onset Sepsis in Neonates: The Nosodiag Study. Frontiers in pediatrics 6: 346	- Outcome to be predicted do not match that specified in the protocol [Reports number with probable infection and with certain infection but statistical outcomes are for both groups combined]
Dilli, Dilek, Oguz, S Suna, Dilmen, Ugur et al. (2010) Predictive values of neutrophil CD64 expression compared with interleukin-6 and C-reactive protein in early diagnosis of neonatal sepsis. Journal of clinical laboratory analysis 24(6): 363-70	- Case-control study

Dollner, H; Vatten, L; Austgulen, R (2001) Early diagnostic markers for neonatal sepsis: comparing C-reactive protein, interleukin-6, soluble tumour necrosis factor receptors and soluble adhesion molecules. <i>Journal of clinical epidemiology</i> 54(12): 1251-7	- Outcome to be predicted do not match that specified in the protocol [Not all sepsis was culture confirmed]
Draz, N.I., Taha, S.E., Abou Shady, N.M. et al. (2013) Comparison of broad range 16S rDNA PCR to conventional blood culture for diagnosis of sepsis in the newborn. <i>Egyptian Journal of Medical Human Genetics</i> 14(4): 403-411	- Not used in current practice
Ehl, S, Gering, B, Bartmann, P et al. (1997) C-reactive protein is a useful marker for guiding duration of antibiotic therapy in suspected neonatal bacterial infection. <i>Pediatrics</i> 99(2): 216-21	- Outcome to be predicted do not match that specified in the protocol [Duration of antibiotics. No information on accuracy]
El-Sonbaty, M.M., AlSharany, W., Youness, E.R. et al. (2016) Diagnostic utility of biomarkers in diagnosis of early stages of neonatal sepsis in neonatal intensive care unit in Egypt. <i>Egyptian Pediatric Association Gazette</i> 64(2): 91-96	- Reference standard in study does not match that specified in protocol [Sensitivity and specificity calculated based on confirmed or suspected sepsis]
Elwan, A.E. and Zarouk, W.A. (2009) Diagnosis of neonatal bacterial sepsis by polymerase chain reaction. <i>Journal of Biological Sciences</i> 9(6): 533-540	- Not used in current practice
Enguix, A, Rey, C, Concha, A et al. (2001) Comparison of procalcitonin with C-reactive protein and serum amyloid for the early diagnosis of bacterial sepsis in critically ill neonates and children. <i>Intensive care medicine</i> 27(1): 211-5	- Case-control study
Ertugrul, Sabahattin, Annagur, Ali, Kurban, Sevil et al. (2013) Comparison of urinary neutrophil gelatinase-associated lipocalin, C-reactive protein and procalcitonin in the diagnosis of late onset sepsis in preterm newborns. <i>The journal of maternal-fetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians</i> 26(4): 430-3	- Conference abstract
Evans, M E, Schaffner, W, Federspiel, C F et al. (1988) Sensitivity, specificity, and predictive value of body surface cultures in a neonatal intensive care unit. <i>JAMA</i> 259(2): 248-52	- Reference standard in study does not match that specified in protocol
Faix, R.G. (2009) Adjustment of cerebrospinal fluid cell counts for a traumatic lumbar puncture does not aid diagnosis of meningitis in neonates. <i>Journal of Pediatrics</i> 155(1): 148-149	- Conference abstract
Fattah, M A, Omer, Al Fadhil A, Asaif, S et al. (2017) Utility of cytokine, adhesion molecule and acute phase proteins in early diagnosis of neonatal sepsis. <i>Journal of natural science, biology, and medicine</i> 8(1): 32-39	- Case-control study
Fendler, Wojciech M and Piotrowski, Andrzej J (2008) Procalcitonin in the early diagnosis of nosocomial sepsis in preterm neonates. <i>Journal of paediatrics and child health</i> 44(3): 114-8	- Outcome to be predicted do not match that specified in the protocol [Suspected sepsis]

Ferrera, P C; Bartfield, J M; Snyder, H S (1997) Neonatal fever: utility of the Rochester criteria in determining low risk for serious bacterial infections. The American journal of emergency medicine 15(3): 299-302	- Assessment tool do not match that specified in the protocol
Fida, Nadia M; Al-Mughales, Jamil A; Fadelallah, Mohamed F (2006) Serum concentrations of interleukin-1 alpha, interleukin-6 and tumor necrosis factor-alpha in neonatal sepsis and meningitis. Saudi medical journal 27(10): 1508-14	- Case-control study
Fleischer, Eduardo, Neuman, Mark I, Wang, Marie E et al. (2019) Cerebrospinal Fluid Profiles of Infants <=60 Days of Age With Bacterial Meningitis. Hospital pediatrics 9(12): 979-982	- Outcome to be predicted does not match that specified in the protocol <i>CSF profiles</i>
Forest JC, Larivière F, Dolcé P et al. (1986) C-reactive protein as biochemical indicator of bacterial infection in neonates. Clinical biochemistry 19(3): 192-194	- Case-control study
Francis, S T, Rawal, S, Roberts, H et al. (2010) Detection of meticillin-resistant staphylococcus aureus (MRSA) colonization in newborn infants using real-time polymerase chain reaction (PCR). Acta paediatrica (Oslo, Norway : 1992) 99(11): 1691-4	- Reference standard in study does not match that specified in protocol [Reference standard is unclear]
Franz, A R, Kron, M, Pohlandt, F et al. (1999) Comparison of procalcitonin with interleukin 8, C-reactive protein and differential white blood cell count for the early diagnosis of bacterial infections in newborn infants. The Pediatric infectious disease journal 18(8): 666-71	- Outcome to be predicted do not match that specified in the protocol [Reports number with culture proven infection and with clinical infection but statistical outcomes are for both groups combined]
Franz, A R, Steinbach, G, Kron, M et al. (1999) Reduction of unnecessary antibiotic therapy in newborn infants using interleukin-8 and C-reactive protein as markers of bacterial infections. Pediatrics 104(3pt1): 447-53	- Outcome to be predicted do not match that specified in the protocol [Reports number with suspected infection and with culture confirmed infection but statistical outcomes are for both groups combined]
Fukuzumi, N., Osawa, K., Sato, I. et al. (2020) Detection of bacterial infection based on age-specific percentile-based reference curve for serum procalcitonin level in preterm infants. Clinical Laboratory 66(12): 105-112	- Outcome to be predicted does not match that specified in the protocol <i>Diagnostic accuracy calculated from infection including dermatitis and pneumonia. Results for sepsis not reported separately</i>
Gerdes, L U, Jorgensen, P E, Nexø, E et al. (1998) C-reactive protein and bacterial meningitis: a meta-analysis. Scandinavian journal of clinical and laboratory investigation 58(5): 383-93	- Systematic review. Reference list checked for possible includes [1 study ordered for full text review]

Ghosh, S; Mittal, M; Jaganathan, G (2001) Early diagnosis of neonatal sepsis using a hematological scoring system. Indian journal of medical sciences 55(9): 495-500	- Not used in current practice
Golden, Stephen M, Stamilio, David M, Faux, Brian M et al. (2004) Evaluation of a real-time fluorescent PCR assay for rapid detection of Group B Streptococci in neonatal blood. Diagnostic microbiology and infectious disease 50(1): 7-13	- Population does not match that specified in the protocol [Population not clearly identified]
Goldfinch, Christopher D, Korman, Tony, Kotsanas, Despina et al. (2018) C-reactive protein and immature-to-total neutrophil ratio have no utility in guiding lumbar puncture in suspected neonatal sepsis. Journal of paediatrics and child health 54(8): 848-854	- Outcome to be predicted do not match that specified in the protocol [Reports number with culture proven infection and with suspected infection but statistical outcomes are for both groups combined]
Goldfinch, Christopher D, Korman, Tony, Kotsanas, Despina et al. (2018) C-reactive protein and immature-to-total neutrophil ratio have no utility in guiding lumbar puncture in suspected neonatal sepsis. Journal of paediatrics and child health 54(8): 848-854	- Outcome to be predicted does not match that specified in the protocol <i>Reports number with suspected infection and with confirmed infection but statistical outcomes are for both groups combined</i>
Gomez, Borja, Diaz, Haydee, Carro, Alba et al. (2019) Performance of blood biomarkers to rule out invasive bacterial infection in febrile infants under 21 days old. Archives of disease in childhood 104(6): 547-551	- Study does not contain any relevant index tests
Greenberg, Rachel G, Smith, P Brian, Cotten, C Michael et al. (2008) Traumatic lumbar punctures in neonates: test performance of the cerebrospinal fluid white blood cell count. The Pediatric infectious disease journal 27(12): 1047-51	- Population does not match that specified in the protocol [Traumatic lumbar punctures]
Groselj-Grenc, Mojca, Ihan, Alojz, Pavcnik-Arnol, Maja et al. (2009) Neutrophil and monocyte CD64 indexes, lipopolysaccharide-binding protein, procalcitonin and C-reactive protein in sepsis of critically ill neonates and children. Intensive care medicine 35(11): 1950-8	- Outcome to be predicted do not match that specified in the protocol [Includes suspected sepsis] - Reference standard in study does not match that specified in protocol [Includes cultures other than blood and CSF]
Hedegaard, Sofie Sommer; Wisborg, Kirsten; Hvas, Anne-Mette (2015) Diagnostic utility of biomarkers for neonatal sepsis--a systematic review. Infectious diseases (London, England) 47(3): 117-24	- Systematic review. Reference list checked for possible includes
Hisamuddin, E., Hisam, A., Wahid, S. et al. (2015) Validity of c-reactive protein (CRP) for diagnosis of neonatal sepsis. Pakistan Journal of Medical Sciences 31(3): 527-531	- Outcome to be predicted do not match that specified in the protocol [Suspected sepsis]

Hornik, Christoph P, Benjamin, Daniel K, Becker, Kristian C et al. (2012) Use of the complete blood cell count in late-onset neonatal sepsis. <i>The Pediatric infectious disease journal</i> 31(8): 803-7	- Reference standard in study does not match that specified in protocol [Blood, CSF or urine culture]
Hristeva, L, Bowler, I, Booy, R et al. (1993) Value of cerebrospinal fluid examination in the diagnosis of meningitis in the newborn. <i>Archives of disease in childhood</i> 69(5specno): 514-7	- Reference standard in study does not match that specified in protocol [Reference standard unclear]
Hsu, Kai-Hsiang, Chiang, Ming-Chou, Lien, Reyin et al. (2014) Limited diagnostic value of routine screening of neonates with the urinary group B streptococcal antigen tests. <i>Pediatrics and neonatology</i> 55(6): 480-6	- Study does not contain any relevant index tests [Urine culture assessing agglutination (GBS antigen test – not test of bacterial culture)]
Isidor, Betrand, Caillaux, Gaelle, Gilquin, Valerie et al. (2007) The use of procalcitonin in the diagnosis of late-onset infection in neonatal intensive care unit patients. <i>Scandinavian journal of infectious diseases</i> 39(1112): 1063-6	- Reference standard in study does not match that specified in protocol [Blood, CSF or urine culture]
Jaswal, R S, Kaushal, R K, Goel, Asha et al. (2003) Role of C-reactive protein in deciding duration of antibiotic therapy in neonatal septicemia. <i>Indian pediatrics</i> 40(9): 880-3	- Reference standard in study does not match that specified in protocol
Kamiab, Z., Hassan, M.R.M., Hassanshahi, G. et al. (2019) The cut-off point of ferritin, procalcitonin, and serum CRP levels in the peripheral blood of neonates suffering from sepsis. <i>Journal of Kerman University of Medical Sciences</i> 26(1): 12-21	- Assessment tool do not match that specified in the protocol [Units of the cut-off for each test not reported]
Kasper, David C, Altioik, Ipek, Mechtler, Thomas P et al. (2013) Molecular detection of late-onset neonatal sepsis in premature infants using small blood volumes: proof-of-concept. <i>Neonatology</i> 103(4): 268-73	- Reference standard in study does not match that specified in protocol
Khassawneh, M, Hayajneh, W A, Kofahi, H et al. (2007) Diagnostic markers for neonatal sepsis: comparing C-reactive protein, interleukin-6 and immunoglobulin M. <i>Scandinavian journal of immunology</i> 65(2): 171-5	- Reference standard in study does not match that specified in protocol [Blood, CSF, urine or other relevant cultures]
Khosravi, N., Khalesi, N., Noorbakhsh, S. et al. (2014) The relationship between cerebrospinal fluid C-reactive protein and neonatal meningitis. <i>Tehran University Medical Journal</i> 71(11): 723-728	- Study not reported in English
Kisban, G; Bartalics, L; Koranyi, G (1985) Diagnostic value of C-reactive protein in premature babies weighing less than 1500 g. <i>Acta paediatrica Hungarica</i> 26(4): 335-40	- Not possible to calculate a contingency table from the data specified in the protocol
Kocabas, Emine, Sarikcioglu, Aysun, Aksaray, Necmi et al. (2007) Role of procalcitonin, C-reactive protein, interleukin-6, interleukin-8 and tumor necrosis factor-alpha in the diagnosis of neonatal sepsis. <i>The Turkish journal of pediatrics</i> 49(1): 7-20	- Case-control study
Kordek, Agnieszka, Loniewska, Beata, Podraza, Wojciech et al. (2014) Usefulness of estimation of blood procalcitonin concentration versus C-reactive protein concentration and white blood cell count for therapeutic monitoring of sepsis in	- Case-control study

neonates. Postepy higieny i medycyny doswiadczonej (Online) 68: 1516-23	
Krediet, T, Gerards, L, Fleer, A et al. (1992) The predictive value of CRP and I/T-ratio in neonatal infection. Journal of perinatal medicine 20(6): 479-85	- Not possible to calculate a contingency table from the data specified in the protocol
Kuppermann, Nathan, Dayan, Peter S, Levine, Deborah A et al. (2019) A Clinical Prediction Rule to Identify Febrile Infants 60 Days and Younger at Low Risk for Serious Bacterial Infections. JAMA pediatrics 173(4): 342-351	- Study does not contain any relevant index tests
Laborada, Gary, Rego, Maria, Jain, Ajey et al. (2003) Diagnostic value of cytokines and C-reactive protein in the first 24 hours of neonatal sepsis. American journal of perinatology 20(8): 491-501	- Outcome to be predicted do not match that specified in the protocol [Definition of sepsis did not fully match the criteria in the protocol]
Lacour, A G, Gervaix, A, Zamora, S A et al. (2001) Procalcitonin, IL-6, IL-8, IL-1 receptor antagonist and C-reactive protein as identifiers of serious bacterial infections in children with fever without localising signs. European journal of pediatrics 160(2): 95-100	- Population does not match that specified in the protocol [Neonates and children. Results for neonates not reported separately]
Liu, Y.; Zhao, L.; Wu, Z. (2019) Accuracy of C-reactive protein test for neonatal septicemia: A diagnostic meta-analysis. Medical Science Monitor 25: 4076-4081	- Systematic review. Reference list checked for possible includes [1 study ordered for full text review]
Makhoul, Imad R, Smolkin, Tatiana, Sujov, Polo et al. (2005) PCR-based diagnosis of neonatal staphylococcal bacteremias. Journal of clinical microbiology 43(9): 4823-5	- Not used in current practice
Makhoul, Imad R, Yacoub, Afeefi, Smolkin, Tatiana et al. (2006) Values of C-reactive protein, procalcitonin, and Staphylococcus-specific PCR in neonatal late-onset sepsis. Acta paediatrica (Oslo, Norway : 1992) 95(10): 1218-23	- Not used in current practice
Mathers, N J and Pohlandt, F (1987) Diagnostic audit of C-reactive protein in neonatal infection. European journal of pediatrics 146(2): 147-51	- Outcome to be predicted do not match that specified in the protocol [Sensitivity and specificity results include suspected infection]
Meehan, M, Cafferkey, M, Corcoran, S et al. (2015) Real-time polymerase chain reaction and culture in the diagnosis of invasive group B streptococcal disease in infants: a retrospective study. European journal of clinical microbiology & infectious diseases : official publication of the European Society of Clinical Microbiology 34(12): 2413-20	- Early-onset neonatal infection
Meem, Mahbuba, Modak, Joyanta K, Mortuza, Roman et al. (2011) Biomarkers for diagnosis of neonatal infections: A systematic analysis of their potential as a point-of-care diagnostics. Journal of global health 1(2): 201-9	- Systematic review. Reference list checked for possible includes
Mustafa, S., Farooqui, S., Waheed, S. et al. (2005) Evaluation of C-reactive protein as early indicator of blood culture positivity in neonates. Pakistan Journal of Medical Sciences 21(1): 69-73	- Assessment tool do not match that specified in the protocol [C-reactive protein but does not state the cut-off value used]

Naher, B S, Mannan, M A, Noor, K et al. (2011) Role of serum procalcitonin and C-reactive protein in the diagnosis of neonatal sepsis. Bangladesh Medical Research Council bulletin 37(2): 40-6	- Reference standard in study does not match that specified in protocol
Nasir, I.A., Mele, H.U., Babayo, A. et al. (2015) Serum Procalcitonin Assay for Investigations and Clinical Management of Neonatal Sepsis: A Review. Journal of Pediatric Infectious Diseases 10(1): 3-11	- Review article but not a systematic review
Natarajan, Girija, Johnson, Yvette R, Zhang, Fan et al. (2006) Real-time polymerase chain reaction for the rapid detection of group B streptococcal colonization in neonates. Pediatrics 118(1): 14-22	- Early-onset neonatal infection
Ng, P C, Cheng, S H, Chui, K M et al. (1997) Diagnosis of late onset neonatal sepsis with cytokines, adhesion molecule, and C-reactive protein in preterm very low birthweight infants. Archives of disease in childhood. Fetal and neonatal edition 77(3): f221-7	- Reference standard in study does not match that specified in protocol
Nnanna, I.I., Ehis, O.J., Sidiquo, I.I. et al. (2011) Serum procalcitonin: Early detection of neonatal bacteremia and septicemia in a tertiary healthcare facility. North American Journal of Medical Sciences 3(3): 157-160	- Reference standard in study does not match that specified in protocol
Numbenjapon, Nawapom, Chamnanwanakij, Sangkae, Sangaroon, Preeyapan et al. (2015) C-reactive protein as a single useful parameter for discontinuation of antibiotic treatment in Thai neonates with clinical sepsis. Journal of the Medical Association of Thailand = Chotmai het thangphaet 98(4): 352-7	- Study design does not match those specified in the protocol
Nuntnarumit, Pracha; Pinkaew, Orawan; Kitiwanwanich, Sureewan (2002) Predictive values of serial C-reactive protein in neonatal sepsis. Journal of the Medical Association of Thailand = Chotmai het thangphaet 85suppl4: 1151-8	- Reference standard in study does not match that specified in protocol [Included suspected sepsis]
Olaciregui, I, Hernandez, U, Munoz, J A et al. (2009) Markers that predict serious bacterial infection in infants under 3 months of age presenting with fever of unknown origin. Archives of disease in childhood 94(7): 501-5	- Outcome to be predicted do not match that specified in the protocol [Multiple sepsis definitions]
Pacifico, L, Chiesa, C, Cianfrano, V et al. (1989) Body surface cultures in the neonatal intensive care unit. JAMA 261(1): 46	- Conference abstract
Pammi, Mohan, Flores, Angela, Leeflang, Mariska et al. (2011) Molecular assays in the diagnosis of neonatal sepsis: a systematic review and meta-analysis. Pediatrics 128(4): e973-85	- Conference abstract
Pammi, Mohan, Flores, Angela, Versalovic, James et al. (2017) Molecular assays for the diagnosis of sepsis in neonates. The Cochrane database of systematic reviews 2: cd011926	- Systematic review. Reference list checked for possible includes
Park, I.H., Lee, S.H., Yu, S.T. et al. (2014) Serum procalcitonin as a diagnostic marker of neonatal sepsis. Korean Journal of Pediatrics 57(10): 440-445	- Outcome to be predicted do not match that specified in the protocol [Sensitivity and specificity results include suspected infection]

Paule, Suzanne M, Pasquariello, Anna C, Hacek, Donna M et al. (2004) Direct detection of <i>Staphylococcus aureus</i> from adult and neonate nasal swab specimens using real-time polymerase chain reaction. <i>The Journal of molecular diagnostics</i> : JMD 6(3): 191-6	- Reference standard in study does not match that specified in protocol [Reference standard unclear]
Pavcnik-Arnol, Maja; Hojker, Sergej; Derganc, Metka (2004) Lipopolysaccharide-binding protein in critically ill neonates and children with suspected infection: comparison with procalcitonin, interleukin-6, and C-reactive protein. <i>Intensive care medicine</i> 30(7): 1454-60	- Population does not match that specified in the protocol [Neonates and children. Neonatal results not reported separately]
Philip AG and Baker CJ (1983) Cerebrospinal fluid C-reactive protein in neonatal meningitis. <i>The Journal of pediatrics</i> 102(5): 715-717	- Reference standard in study does not match that specified in protocol [No clear definition of confirmed infection]
Pourcyrous, M, Bada, H S, Korones, S B et al. (1993) Significance of serial C-reactive protein responses in neonatal infection and other disorders. <i>Pediatrics</i> 92(3): 431-5	- Outcome to be predicted do not match that specified in the protocol [Does not include accuracy data]
Pravin Charles, Marie Victor, Kalaivani, Ramakrishnan, Venkatesh, Soma et al. (2018) Evaluation of procalcitonin as a diagnostic marker in neonatal sepsis. <i>Indian journal of pathology & microbiology</i> 61(1): 81-84	- Reference standard in study does not match that specified in protocol [Unclear whether reference standard includes suspected sepsis as well as confirmed]
Prince, K.; Omar, F.; Joolay, Y. (2019) A Comparison of Point of Care C-Reactive Protein Test to Standard C-Reactive Protein Laboratory Measurement in a Neonatal Intensive Care Unit Setting. <i>Journal of Tropical Pediatrics</i> 65(5): 498-504	- Full text paper not available
Pugni, Lorenza, Pietrasanta, Carlo, Milani, Silvano et al. (2015) Presepsin (Soluble CD14 Subtype): Reference Ranges of a New Sepsis Marker in Term and Preterm Neonates. <i>PLoS one</i> 10(12): e0146020	- Not used in current practice
Quadir, Ashfaque F and Britton, Philip N (2018) Procalcitonin and C-reactive protein as biomarkers for neonatal bacterial infection. <i>Journal of paediatrics and child health</i> 54(6): 695-699	- Systematic review. Reference list checked for possible includes
Rashwan, Nagwan I, Hassan, Mohammed H, Mohey El-Deen, Zeinab M et al. (2019) Validity of biomarkers in screening for neonatal sepsis - A single center -hospital based study. <i>Pediatrics and neonatology</i> 60(2): 149-155	- Case-control study
Raul Bustos, B. and Heriberto Araneda, C. (2012) Procalcitonin for the diagnosis of late onset sepsis in newborns of very low birth weight. <i>Revista Chilena de Infectologia</i> 29(5): 511-516	- Study not reported in English
Reshi, Z, Nazir, M, Wani, W et al. (2017) Cerebrospinal fluid procalcitonin as a biomarker of bacterial meningitis in neonates. <i>Journal of perinatology : official journal of the California Perinatal Association</i> 37(8): 927-931	- Outcome to be predicted do not match that specified in the protocol [Neonates with sepsis who developed meningitis]

Rodwell, R L; Leslie, A L; Tudehope, D I (1988) Early diagnosis of neonatal sepsis using a hematologic scoring system. <i>The Journal of pediatrics</i> 112(5): 761-7	- Assessment tool do not match that specified in the protocol
Rohit, Anusha, Maiti, Biswajit, Shenoy, Shalini et al. (2016) Polymerase chain reaction-restriction fragment length polymorphism (PCR-RFLP) for rapid diagnosis of neonatal sepsis. <i>The Indian journal of medical research</i> 143(1): 72-8	- Not used in current practice
Russell, G A; Smyth, A; Cooke, R W (1992) Receiver operating characteristic curves for comparison of serial neutrophil band forms and C reactive protein in neonates at risk of infection. <i>Archives of disease in childhood</i> 67(7specno): 808-12	- Outcome to be predicted do not match that specified in the protocol [Includes clinical infection as well as confirmed]
Saied, D.A. (2018) Can we rely on the neutrophil left shift for the diagnosis of neonatal sepsis? Need for re-evaluation. <i>Egyptian Pediatric Association Gazette</i> 66(1): 22-27	- Reference standard in study does not match that specified in protocol [Positive blood cultures or laboratory findings that were not specified in protocol]
Shaat, Samar S, El Shazly, Soraya A, Badr Eldin, Mohamed M et al. (2013) Role of polymerase chain reaction as an early diagnostic tool for neonatal bacterial sepsis. <i>The Journal of the Egyptian Public Health Association</i> 88(3): 160-4	- Not used in current practice
Shabuj, K H, Hossain, J, Moni, S C et al. (2017) C-reactive Protein (CRP) as a Single Biomarker for Diagnosis of Neonatal Sepsis: A Comprehensive Meta-analysis. <i>Mymensingh medical journal</i> : MMJ 26(2): 364-371	- Systematic review. Reference list checked for possible includes
Sharma, Deepak, Farahbakhsh, Nazanin, Shastri, Sweta et al. (2018) Biomarkers for diagnosis of neonatal sepsis: a literature review. <i>The journal of maternal-fetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians</i> 31(12): 1646-1659	- Systematic review. Reference list checked for possible includes
Shi, Jing; Tang, Jun; Chen, Dapeng (2016) Meta-analysis of diagnostic accuracy of neutrophil CD64 for neonatal sepsis. <i>Italian journal of pediatrics</i> 42(1): 57	- Systematic review. Reference list checked for possible includes
Sorsa, A. (2018) Diagnostic significance of white blood cell count and C-reactive protein in neonatal sepsis; Asella referral hospital, south east Ethiopia. <i>Open Microbiology Journal</i> 12(1): 209-217	- Reference standard in study does not match that specified in protocol [Risk factors or clinical features but not culture confirmed]
Srinivasan, Lakshmi, Kilpatrick, Laurie, Shah, Samir S et al. (2018) Elevations of novel cytokines in bacterial meningitis in infants. <i>PloS one</i> 13(2): e0181449	- Case-control study
Topuz, S. and Ovali, F. (2012) Comparison of C-reactive protein and procalcitonin in the diagnosis of neonatal sepsis. <i>Nobel Medicus</i> 8(1): 72-76	- Study not reported in English
Turner, Dan, Hammerman, Cathy, Rudensky, Bernard et al. (2006) The role of procalcitonin as a predictor of nosocomial sepsis in preterm infants. <i>Acta paediatrica (Oslo, Norway : 1992)</i> 95(12): 1571-6	- Reference standard in study does not match that specified in protocol [Blood, CSF or urine culture]

van den Brand, Marre, van den Dungen, Frank A M, Bos, Martine P et al. (2018) Evaluation of a real-time PCR assay for detection and quantification of bacterial DNA directly in blood of preterm neonates with suspected late-onset sepsis. <i>Critical care</i> (London, England) 22(1): 105	- Outcome to be predicted do not match that specified in the protocol [Sensitivity and specificity results include suspected infection]
Vazzalwar R, Pina-Rodrigues E, Puppala BL et al. (2005) Procalcitonin as a screening test for late-onset sepsis in preterm very low birth weight infants. <i>Journal of perinatology : official journal of the California Perinatal Association</i> 25(6): 397-402	- Reference standard in study does not match that specified in protocol [Positive blood, urine or CSF culture]
Vouloumanou, Evridiki K, Plessa, Eleni, Karageorgopoulos, Drosos E et al. (2011) Serum procalcitonin as a diagnostic marker for neonatal sepsis: a systematic review and meta-analysis. <i>Intensive care medicine</i> 37(5): 747-62	- Systematic review. Reference list checked for possible includes
Wagle, S, Grauaug, A, Kohan, R et al. (1994) C-reactive protein as a diagnostic tool of sepsis in very immature babies. <i>Journal of paediatrics and child health</i> 30(1): 40-4	- Reference standard in study does not match that specified in protocol [Blood, CSF or urine culture]
Wasunna, A, Whitelaw, A, Gallimore, R et al. (1990) C-reactive protein and bacterial infection in preterm infants. <i>European journal of pediatrics</i> 149(6): 424-7	- Early-onset neonatal infection
Wen, N., Shi, J., Wu, J. et al. (2019) The application of PCT and CRP combined with 16s rRNA in the early diagnosis of neonatal septicemia. <i>International Journal of Clinical and Experimental Medicine</i> 12(11): 12861-12867	- Study does not contain any relevant index tests <i>Index test not used in UK</i>
Xu, L., Li, Q., Mo, Z. et al. (2016) Diagnostic value of C-reactive protein in neonatal sepsis: A meta-analysis. <i>European Journal of Inflammation</i> 14(2): 100-108	- Systematic review. Reference list checked for possible includes
Ye, Qing, Du, Li-Zhong, Shao, Wen-Xia et al. (2017) Utility of cytokines to predict neonatal sepsis. <i>Pediatric research</i> 81(4): 616-621	- Case-control study
Yu, Zhangbin, Liu, Jiebo, Sun, Qing et al. (2010) The accuracy of the procalcitonin test for the diagnosis of neonatal sepsis: a meta-analysis. <i>Scandinavian journal of infectious diseases</i> 42(10): 723-33	- Systematic review. Reference list checked for possible includes
Zawar, M P, Tambekar, R G, Deshpande, N M et al. (2003) Early diagnosis of neonatal septicemia by sepsis screen. <i>Indian journal of pathology & microbiology</i> 46(4): 610-2	- Reference standard in study does not match that specified in protocol [Definition for infection is unclear]
Zecca, Enrico, Barone, Giovanni, Corsello, Mirta et al. (2009) Reliability of two different bedside assays for C-reactive protein in newborn infants. <i>Clinical chemistry and laboratory medicine</i> 47(9): 1081-4	- Reference standard in study does not match that specified in protocol [Blood, CSF or urine culture]